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(12) **United States Patent**
Sweeney

(10) **Patent No.: US 9,445,852 B2**
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(54) **METHOD AND DEVICE FOR DELIVERING MEDICINE TO BONE**

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(21) Appl. No.: **13/270,072**

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(65) **Prior Publication Data**

US 2012/0029432 A1 Feb. 2, 2012

Related U.S. Application Data

(63) Continuation of application No. 12/822,022, filed on Jun. 23, 2010, now Pat. No. 8,062,270, which is a continuation-in-part of application No. 12/427,520, filed on Apr. 21, 2009, which is a continuation of

(Continued)

(51) **Int. Cl.**
A61B 17/86 (2006.01)
A61B 17/34 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61B 17/864*** (2013.01); ***A61B 17/3472*** (2013.01); ***A61B 17/7061*** (2013.01); ***A61B 17/8685*** (2013.01); ***A61B 17/8819*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC A61B 17/72; A61B 17/864; A61B 17/7258; A61B 17/744; A61B 17/3472; A61B 17/7061; A61B 17/7098; A61B 17/8685; A61B 2017/0004; A61F 2002/30677; A61M 2025/0175; A61M 25/0194
USPC 604/101.01, 101.03, 101.04, 175, 264; 606/60, 62, 80, 93, 313, 314
See application file for complete search history.

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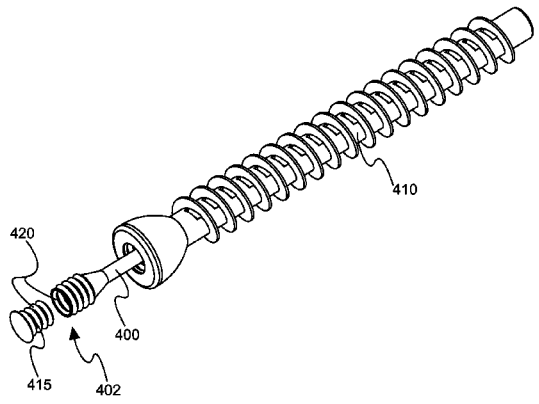
(57) **ABSTRACT**

A system for treating a bone includes an insert for a bone screw or a fixation nail. The insert includes a shaft that extends between proximal and distal ends of the insert and a cap. The shaft includes an opening in the proximal end and a cannulation extending from the opening through at least a portion of the shaft. The shaft further includes a fenestration disposed along the cannulation such that the cannulation is configured to provide a pathway for a substance between the opening and the fenestration. The cap is fastened to and seals the opening in the proximal end of the shaft and adjoins the cannulation. The cap is configured to provide a needle access through the cap to the cannulation following implantation of the system within the bone, and is further configured to self-seal after the needle is removed.

8 Claims, 35 Drawing Sheets



Related U.S. Application Data

application No. 10/704,526, filed on Nov. 7, 2003, now Pat. No. 7,527,611, which is a continuation-in-part of application No. 10/620,287, filed on Jul. 15, 2003, now Pat. No. 7,575,572, and a continuation-in-part of application No. 10/682,307, filed on Oct. 9, 2003, now Pat. No. 7,608,062.

(51) **Int. Cl.**

A61B 17/70	(2006.01)
A61B 17/88	(2006.01)
A61M 37/00	(2006.01)
A61B 17/72	(2006.01)
A61B 17/74	(2006.01)
A61B 17/00	(2006.01)
A61F 2/30	(2006.01)

(52) **U.S. Cl.**

CPC ***A61B 17/8841*** (2013.01); ***A61M 37/00*** (2013.01); *A61B 17/7098* (2013.01); *A61B 17/72* (2013.01); *A61B 17/7258* (2013.01); *A61B 17/744* (2013.01); *A61B 2017/00004* (2013.01); *A61F 2002/30677* (2013.01)

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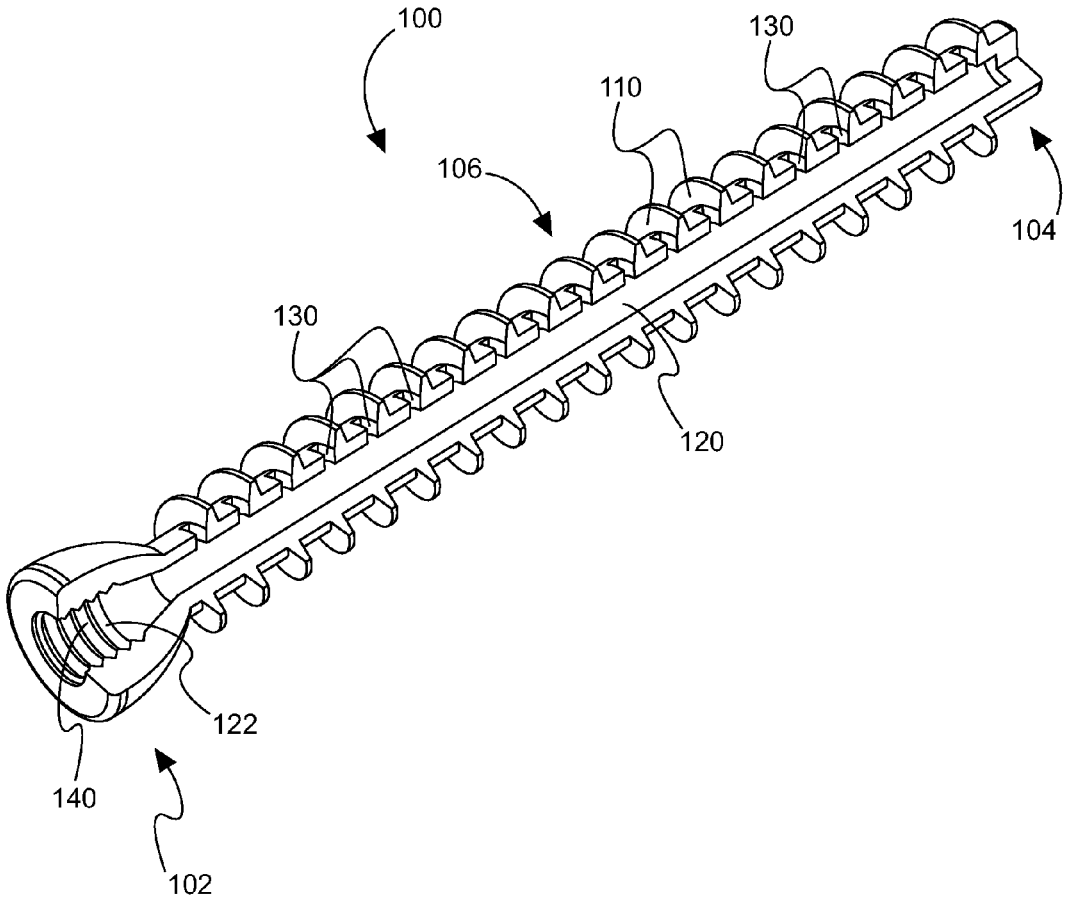


Fig. 1

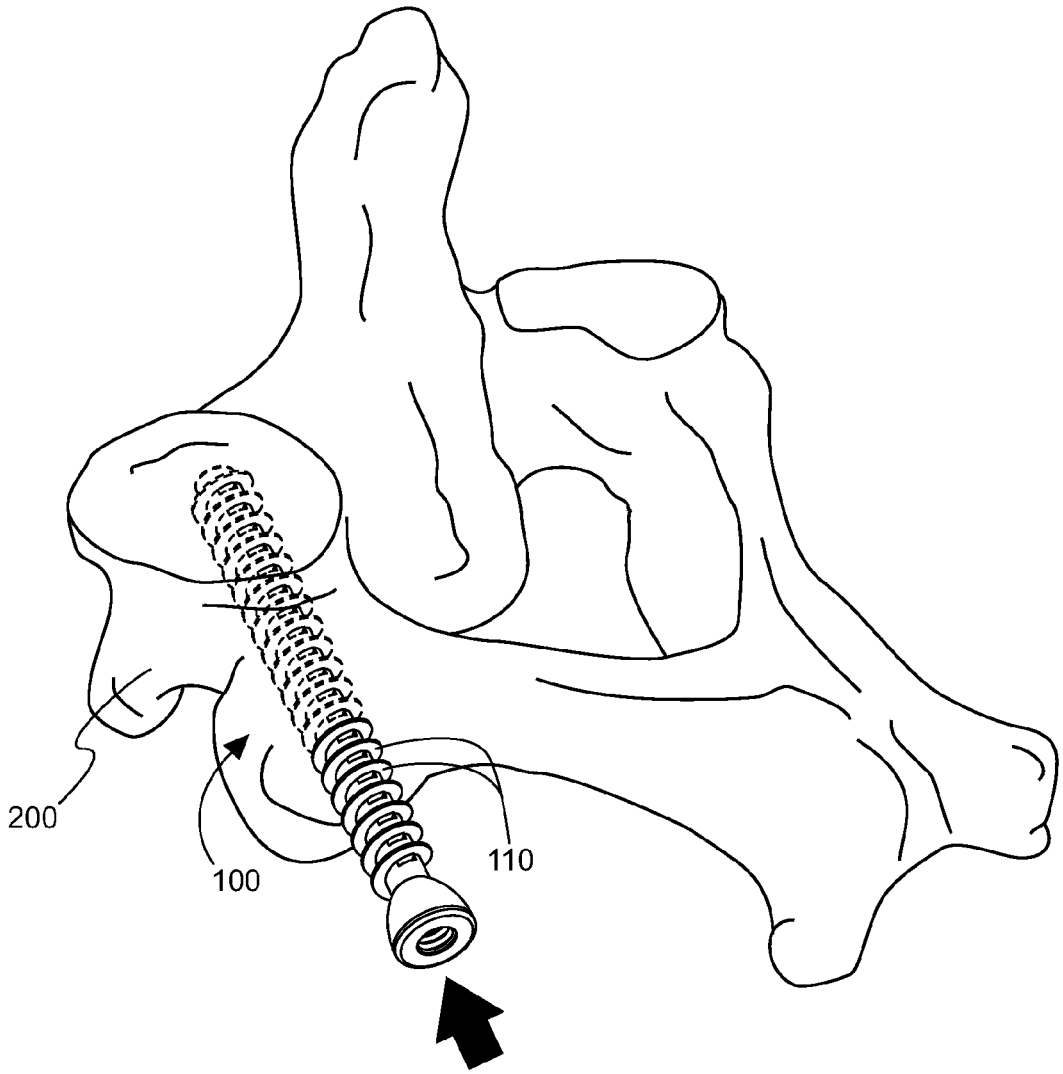


Fig. 2

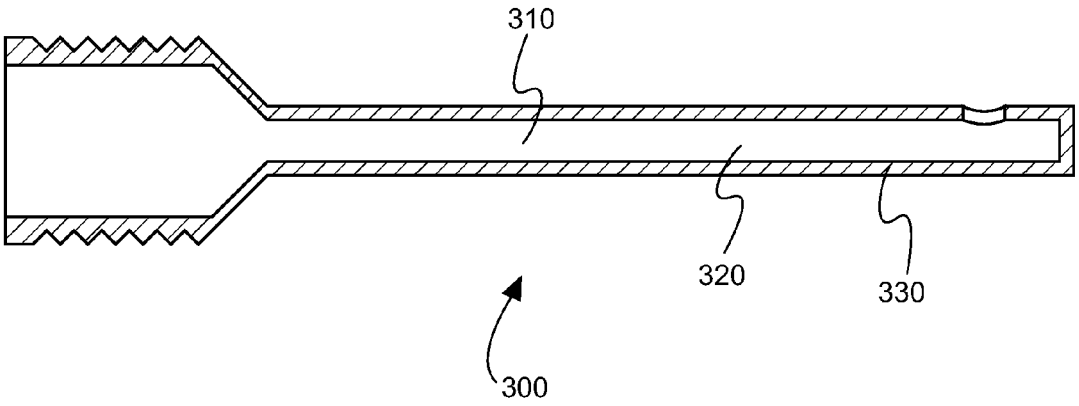


Fig. 3(a)

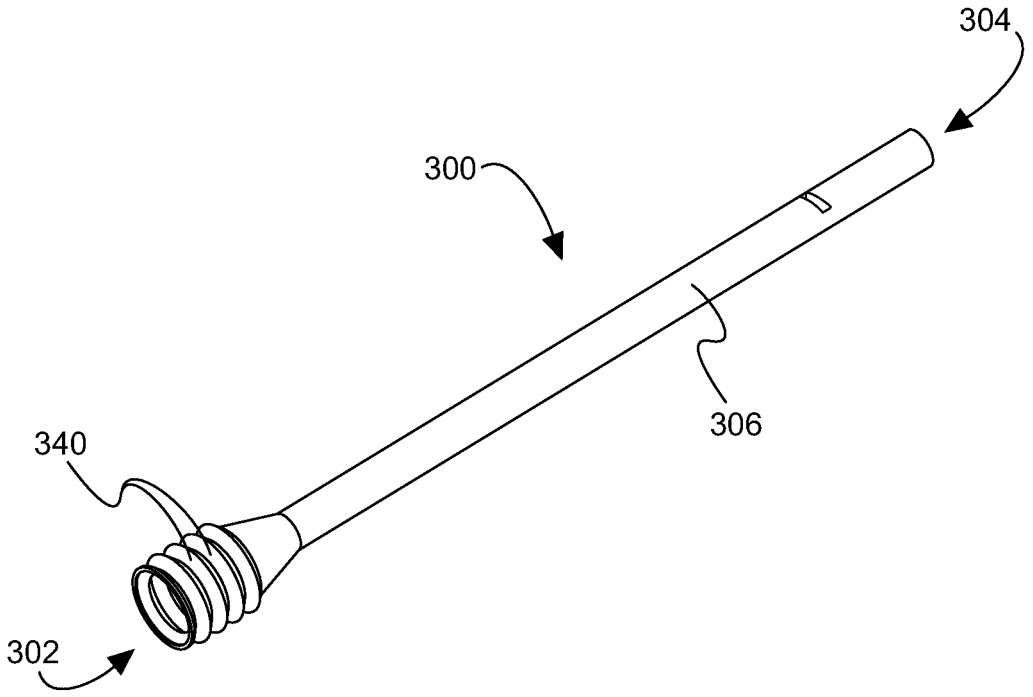
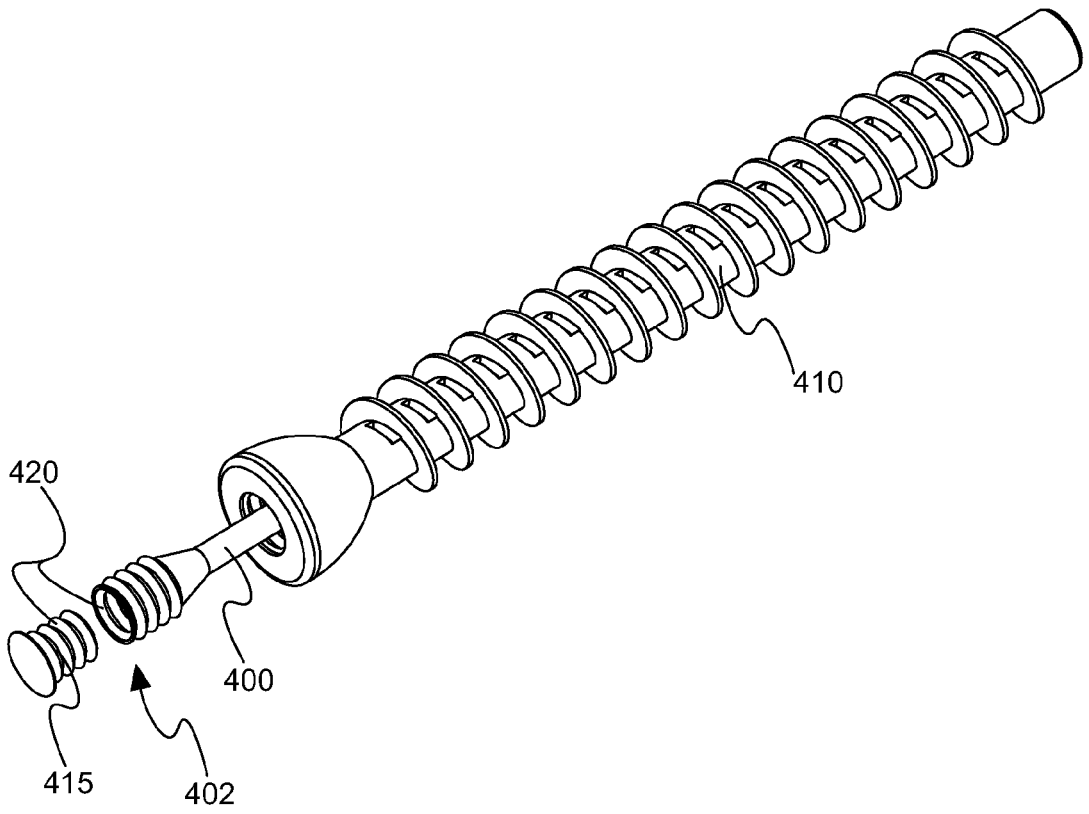


Fig. 3(b)



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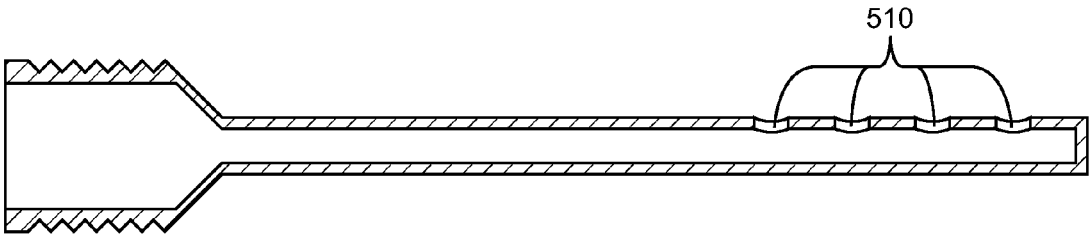
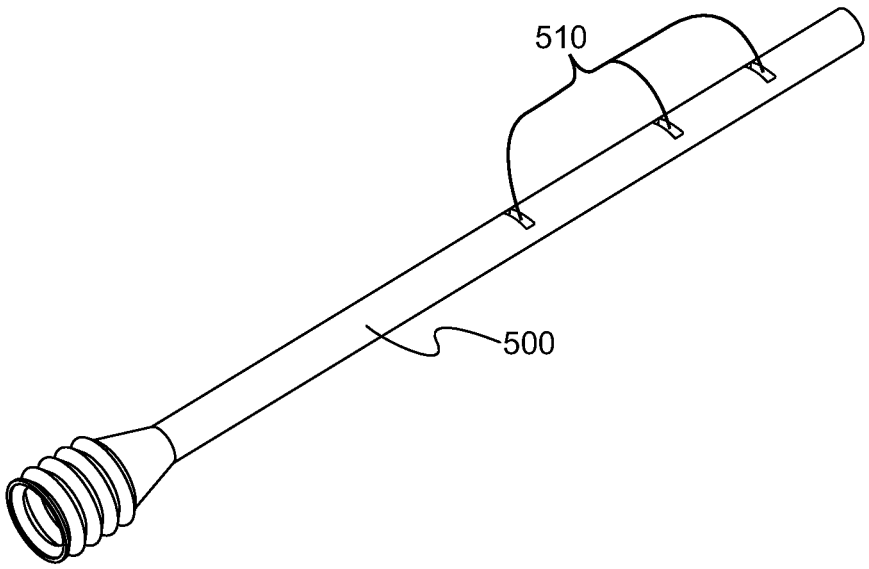


Fig. 5(a)



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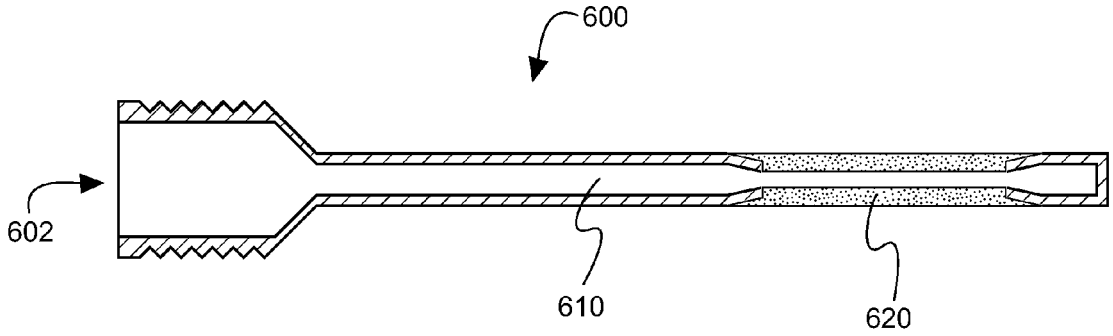

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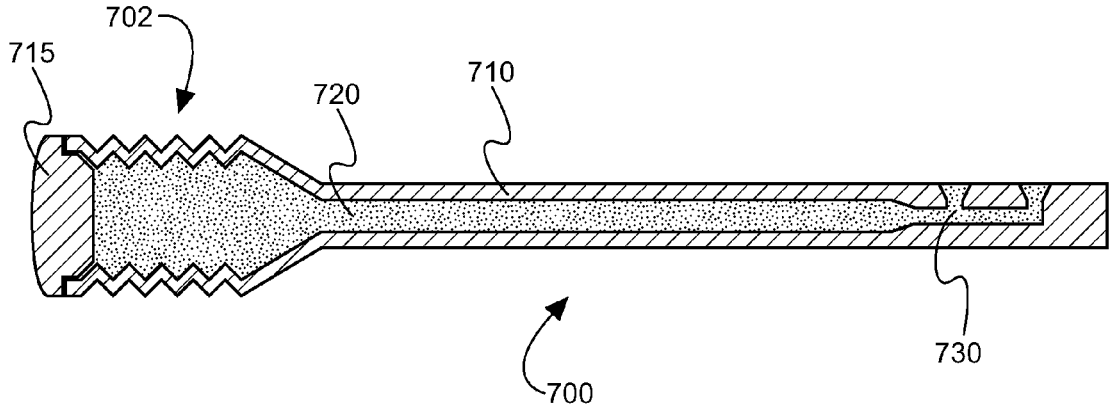

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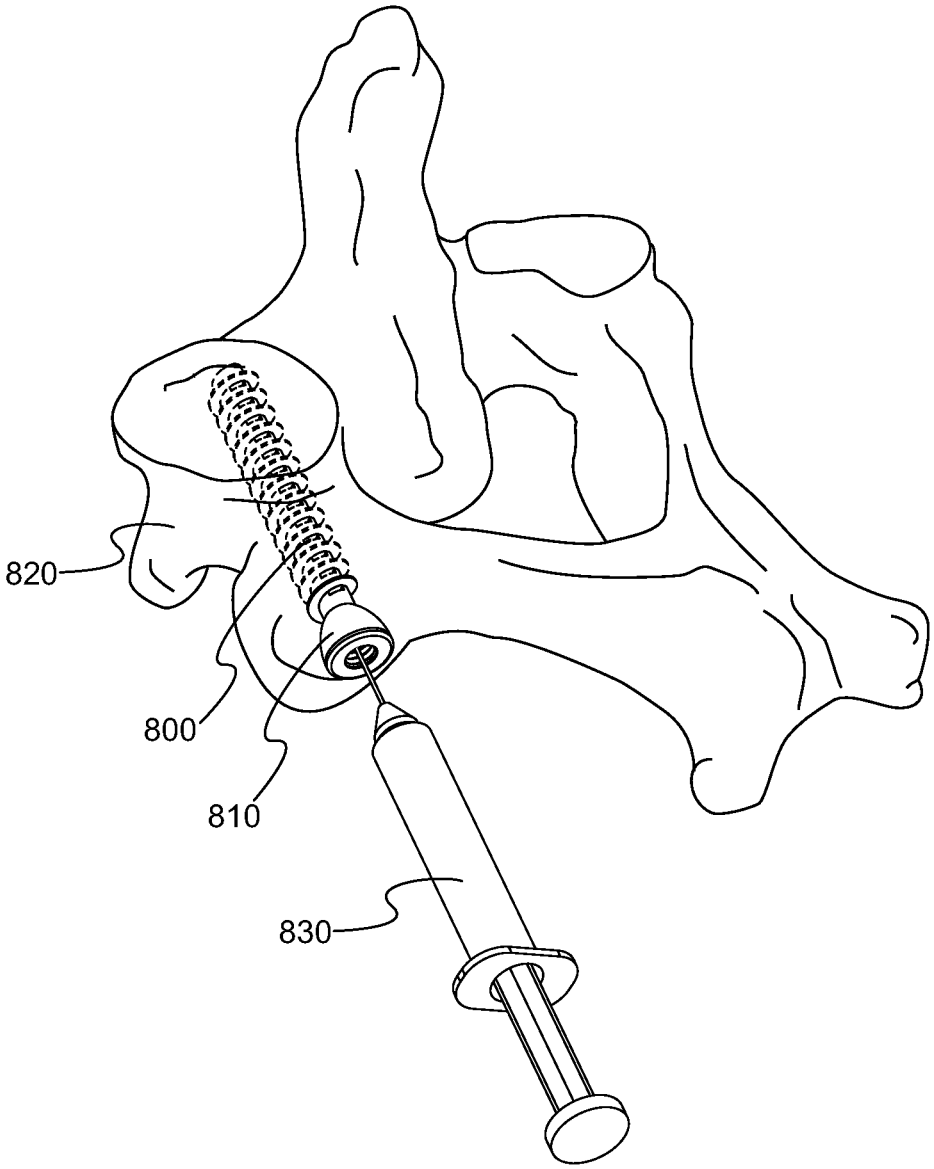

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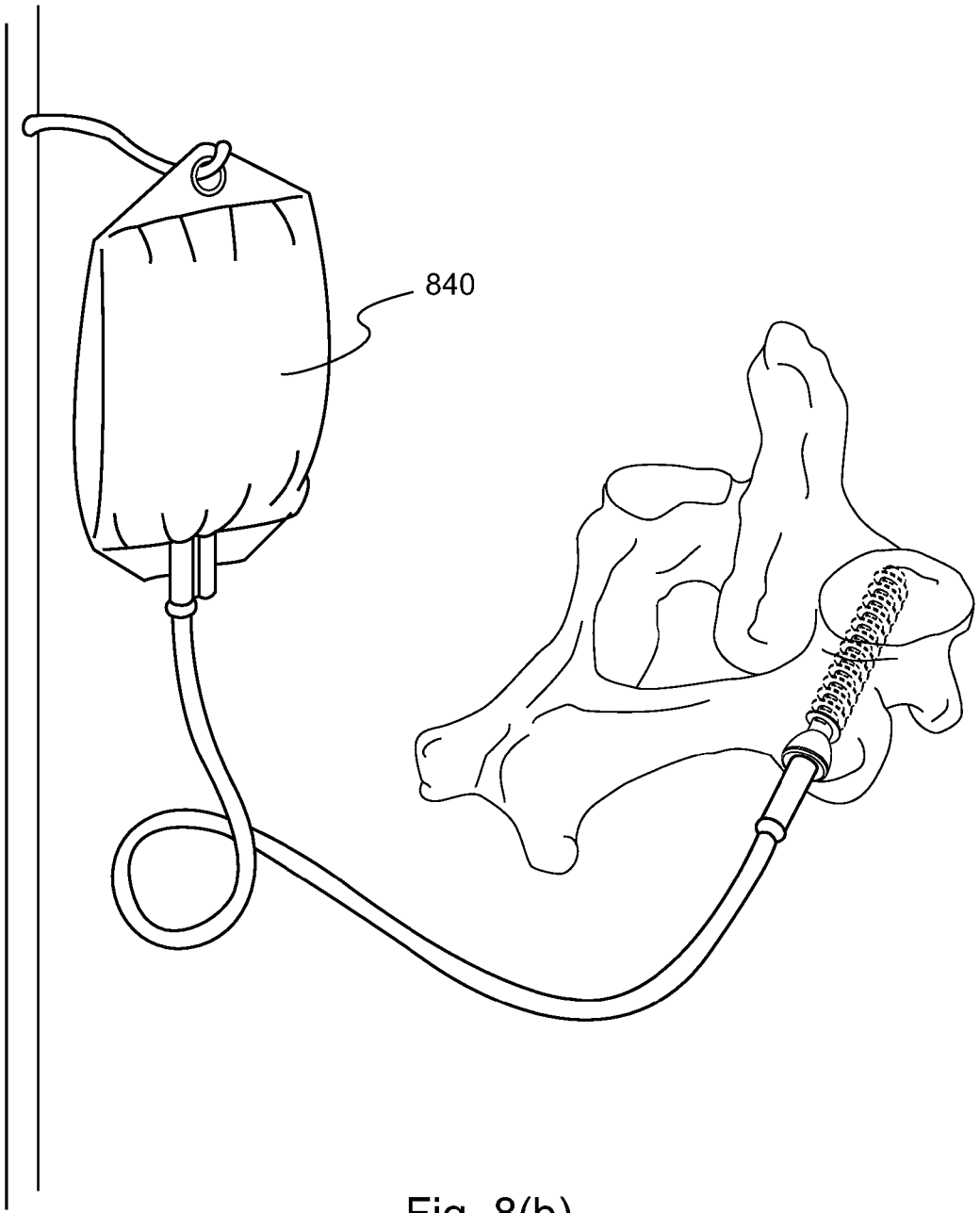

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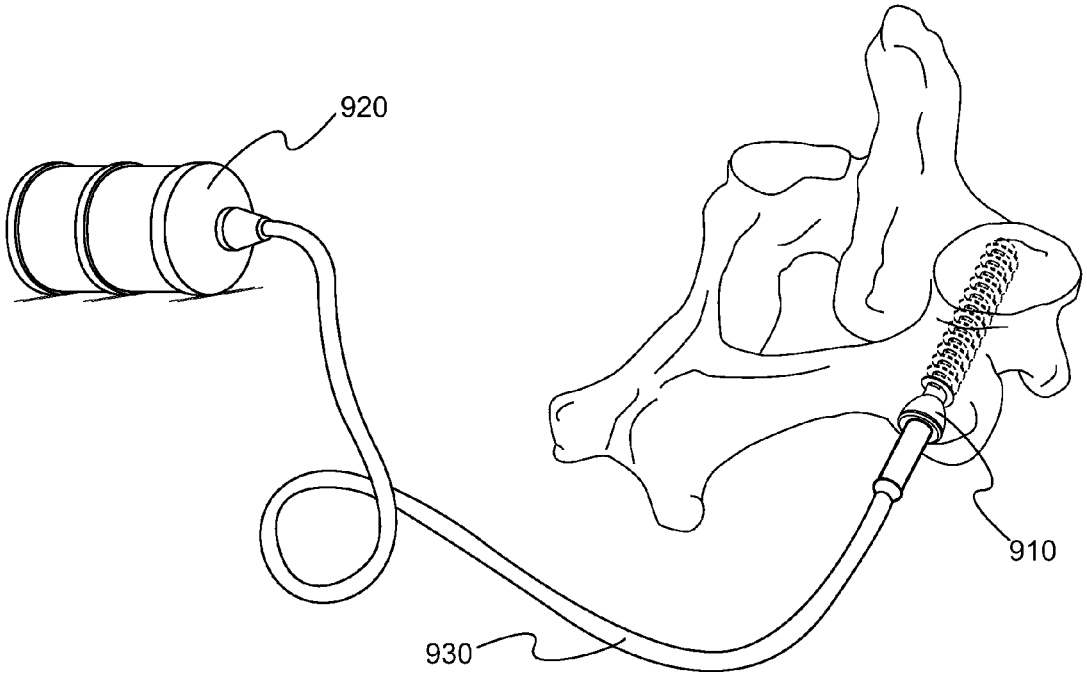

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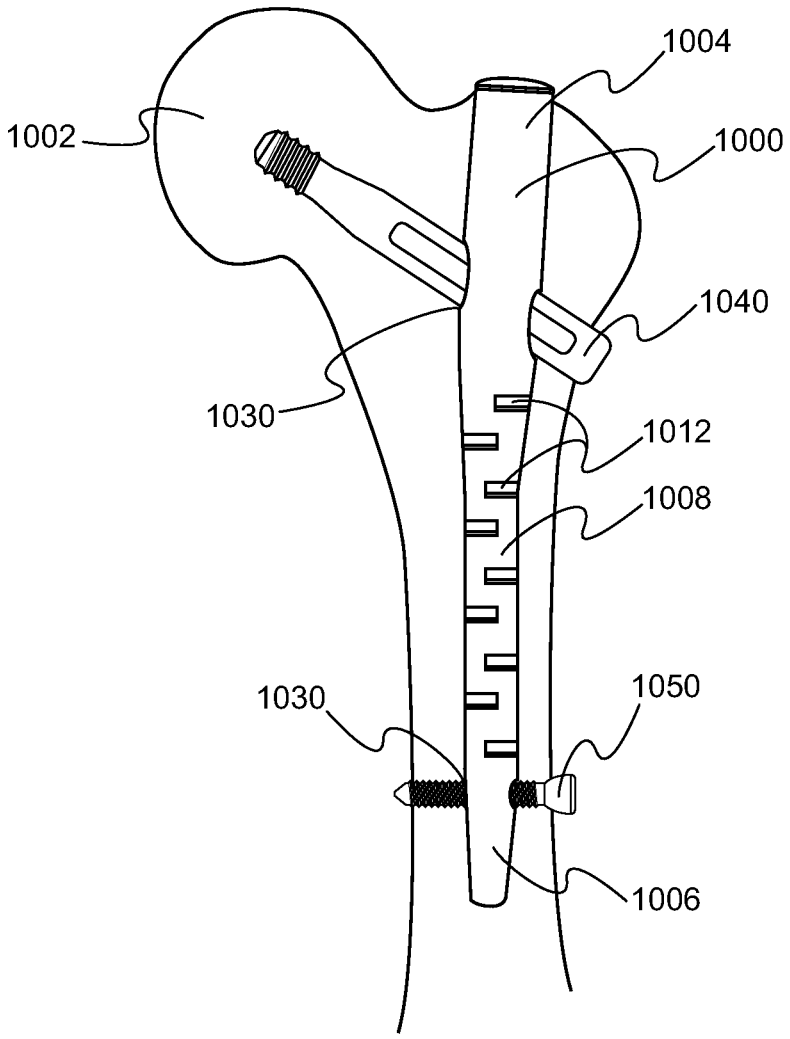

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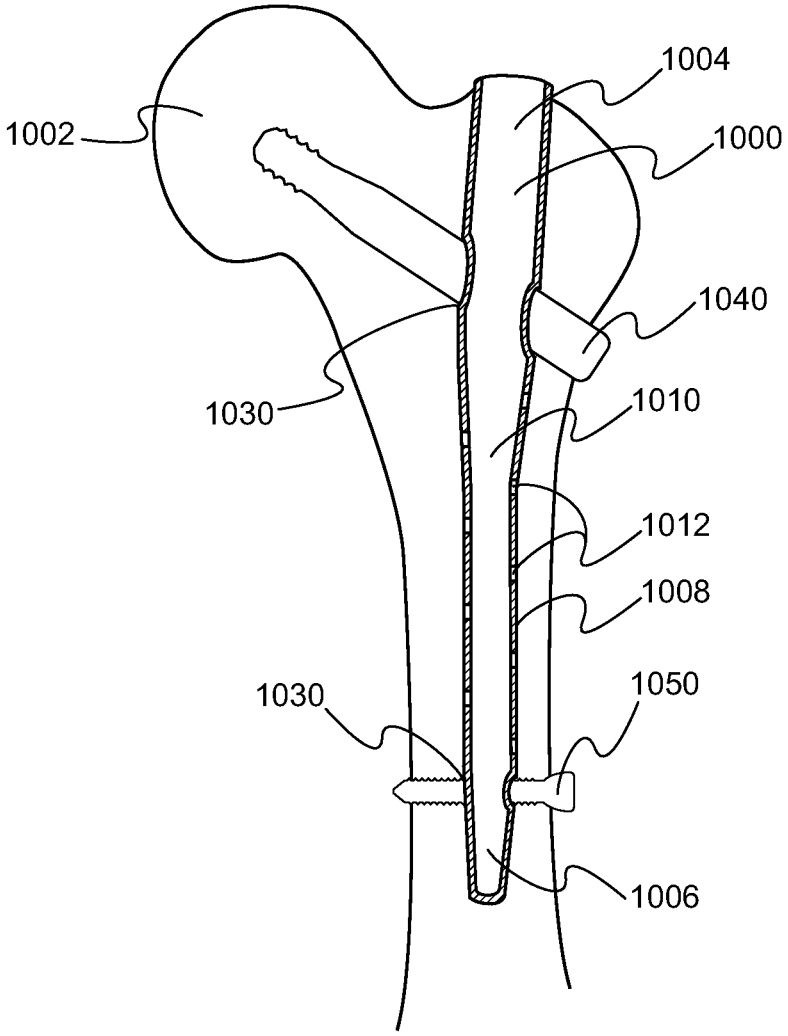

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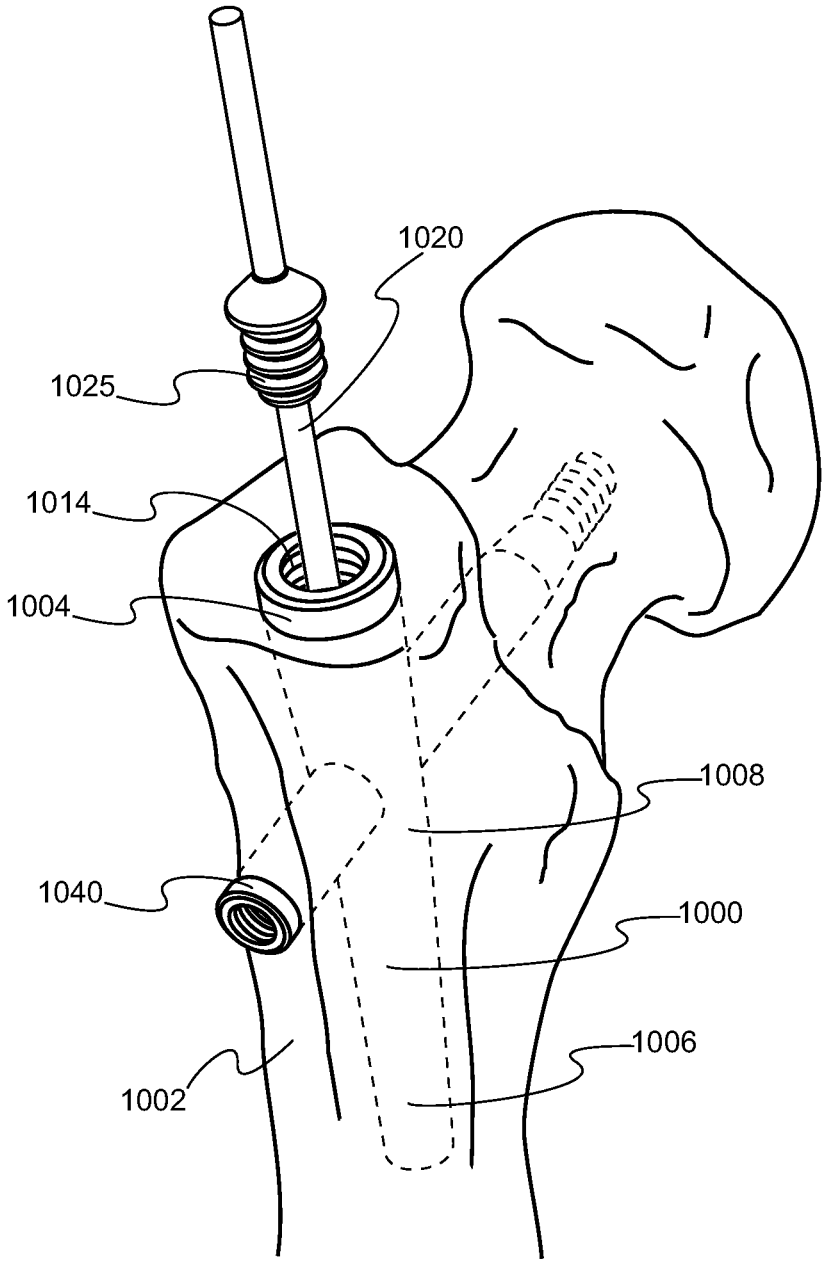

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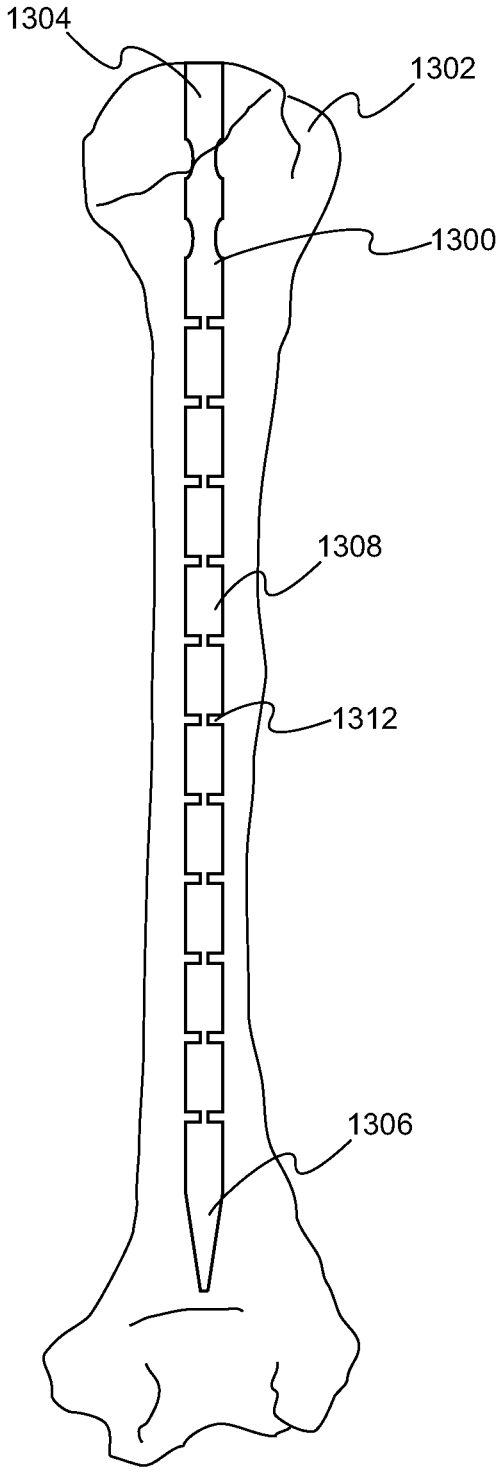

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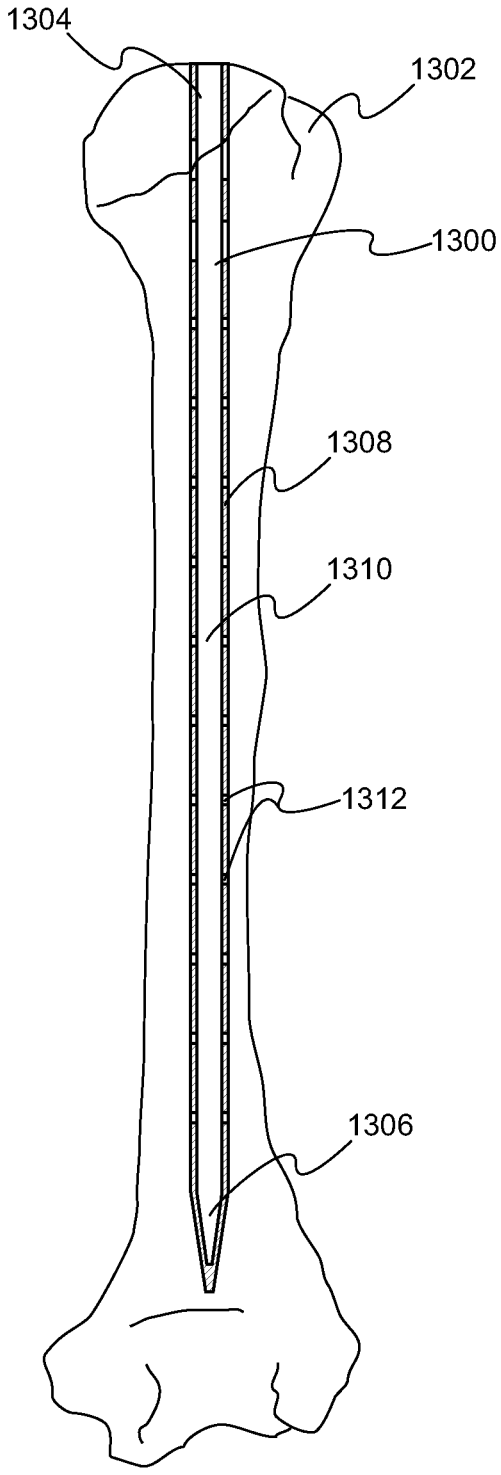

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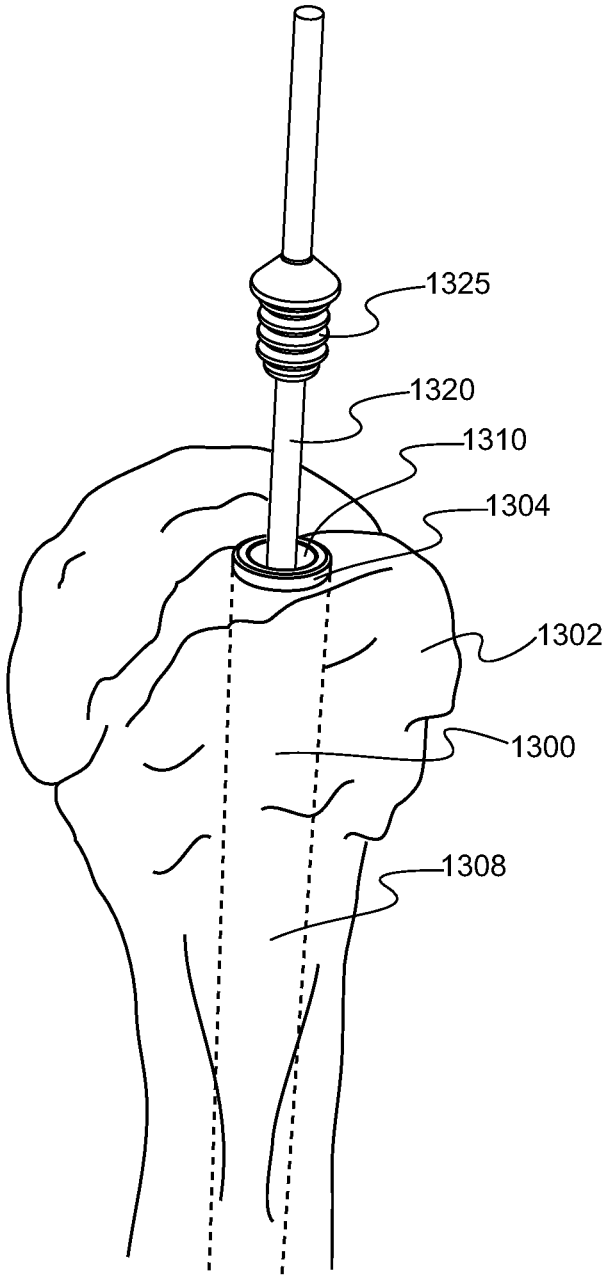

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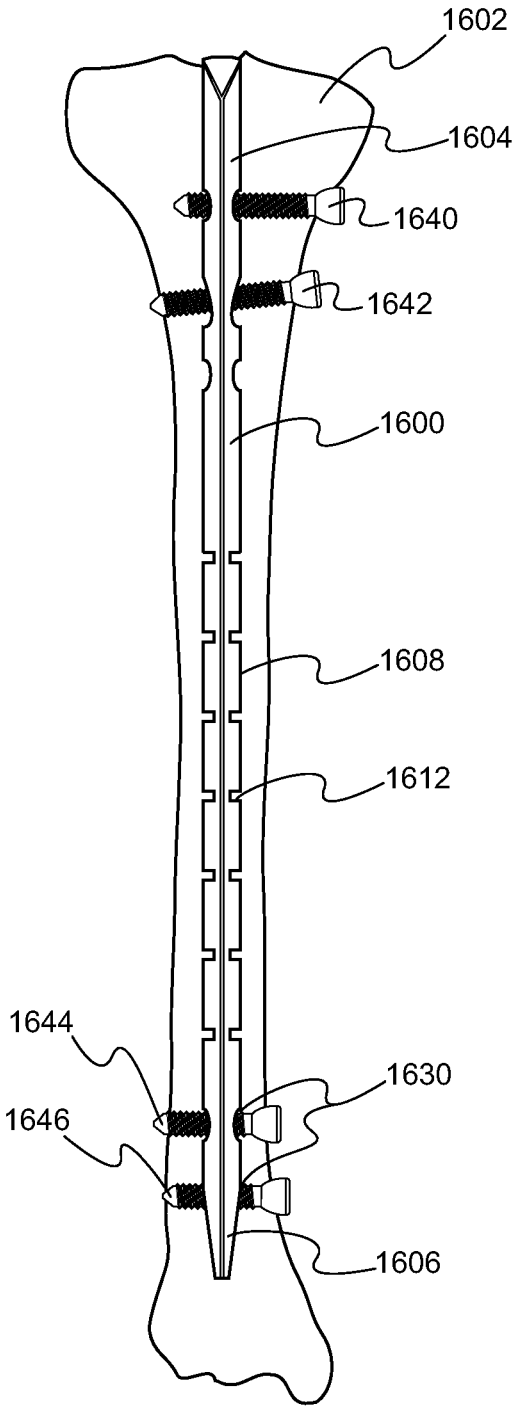

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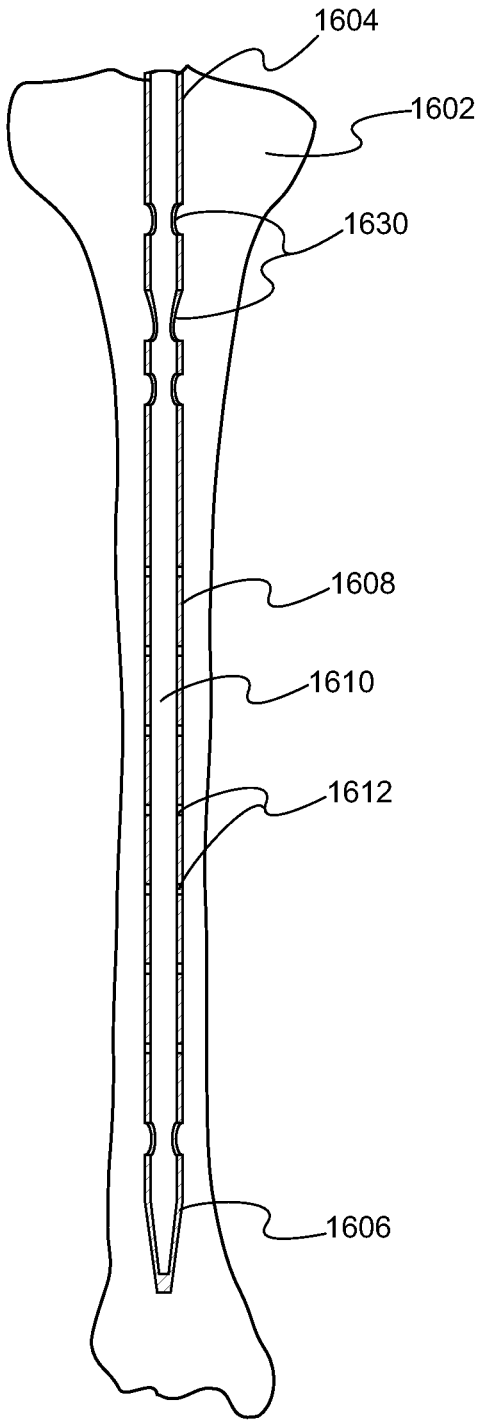

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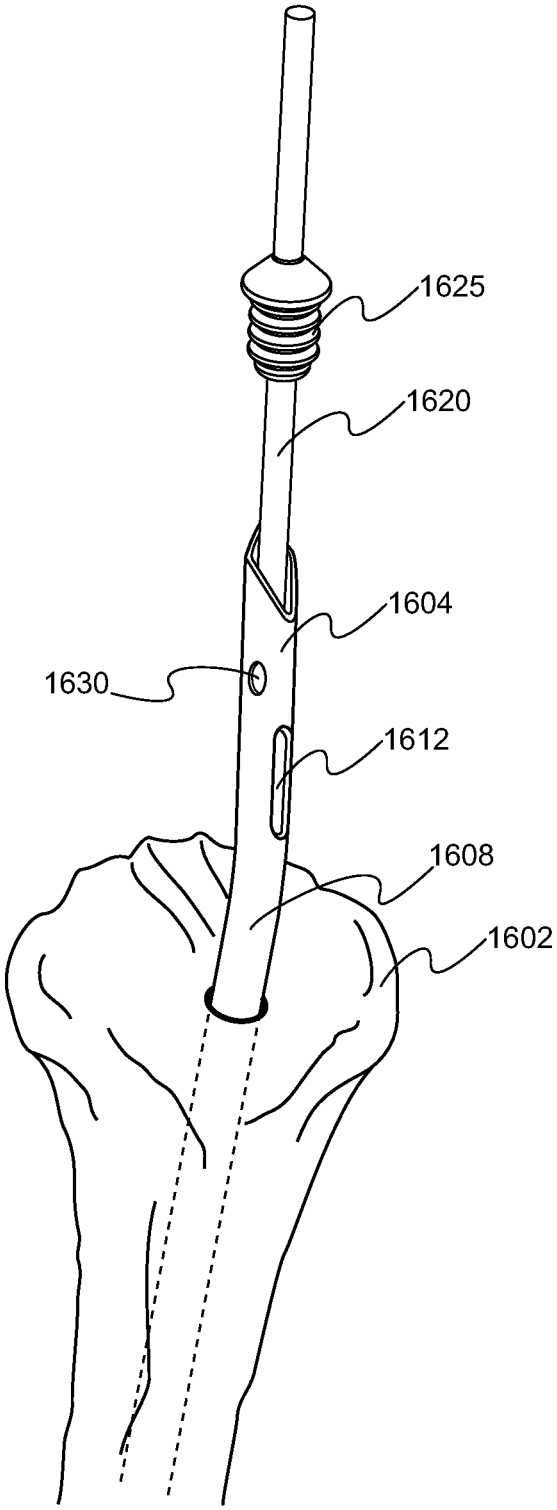

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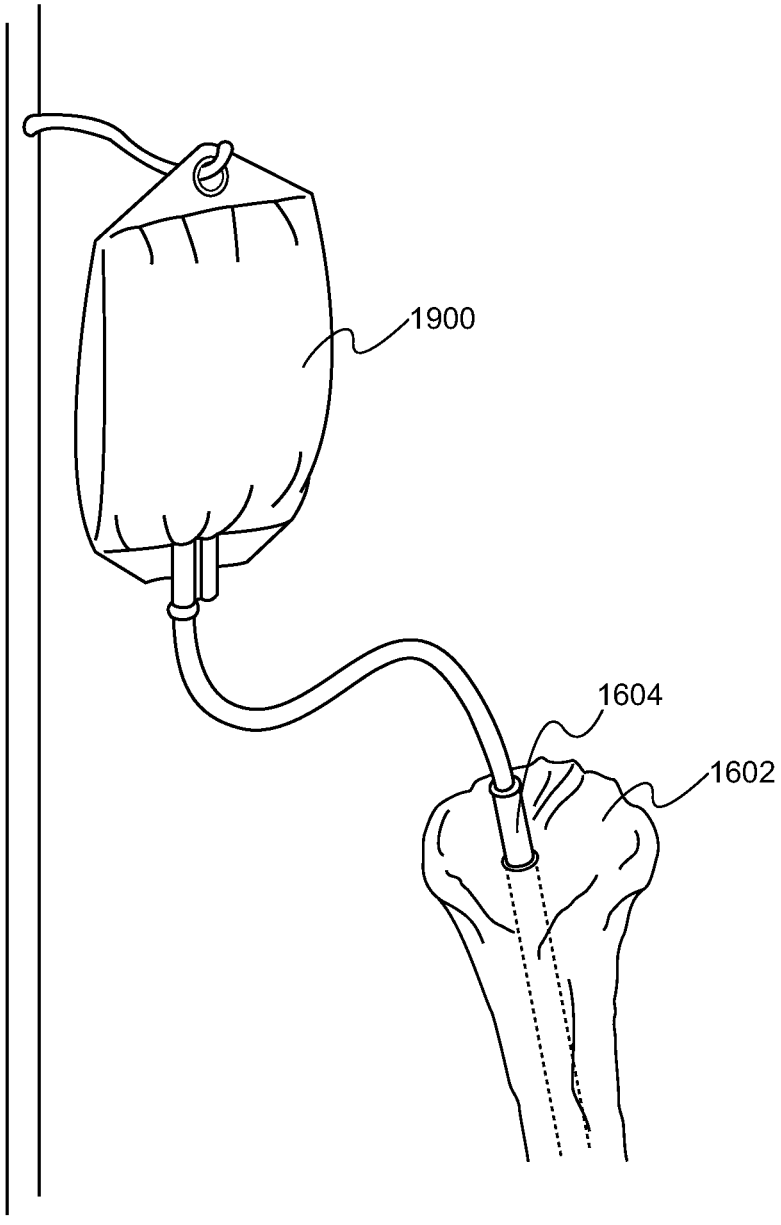

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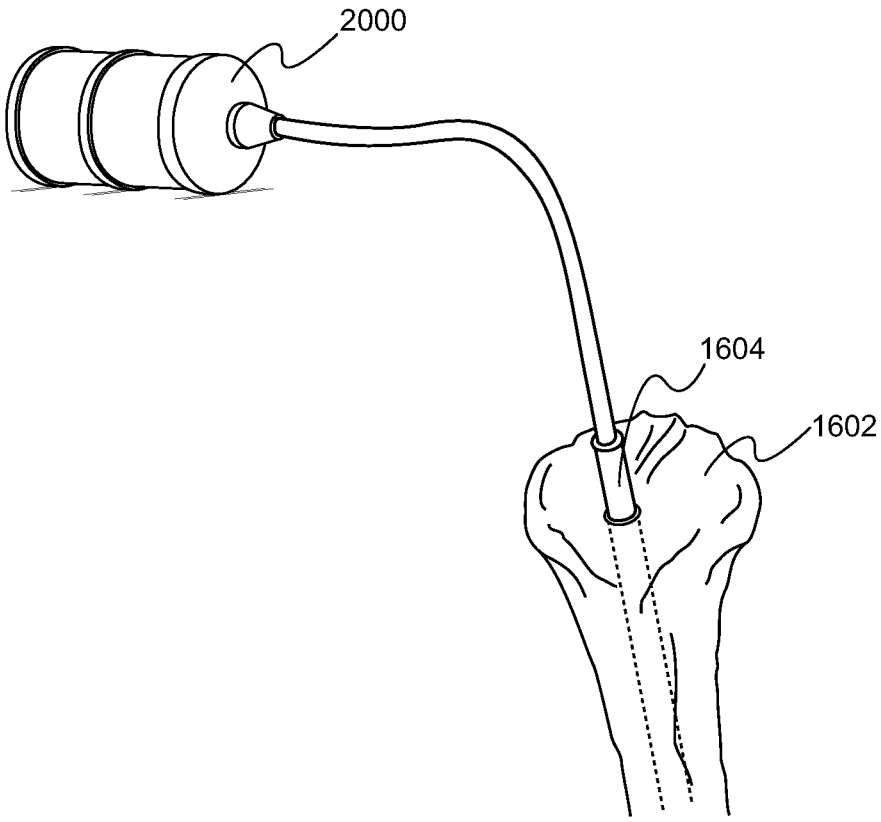

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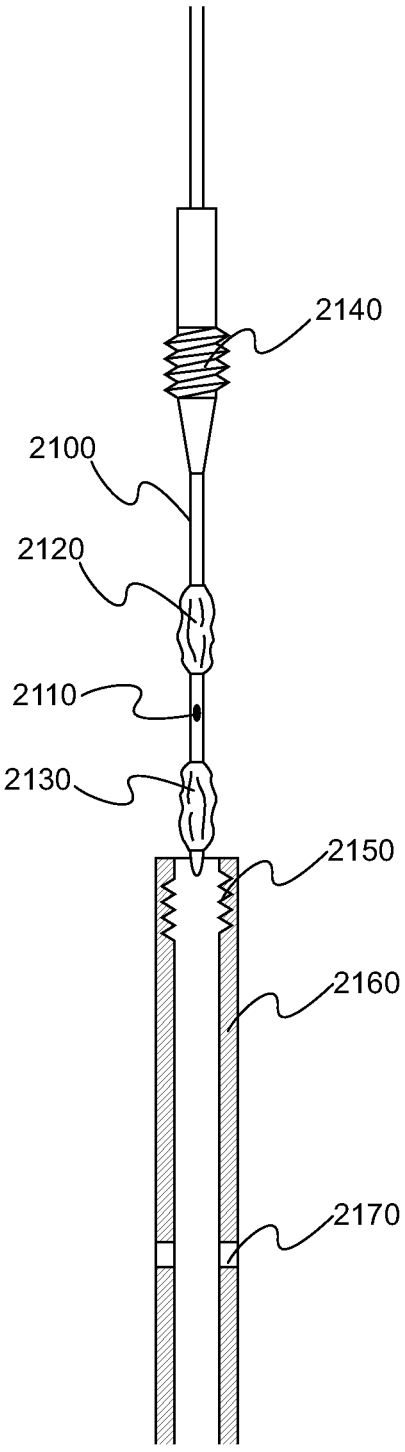
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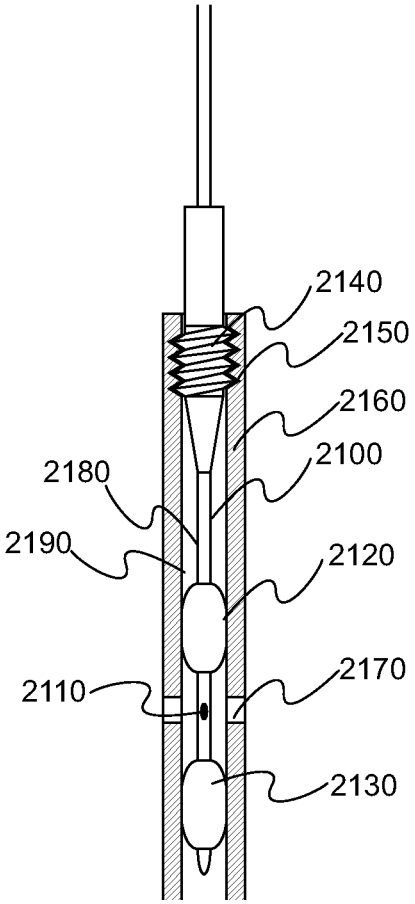
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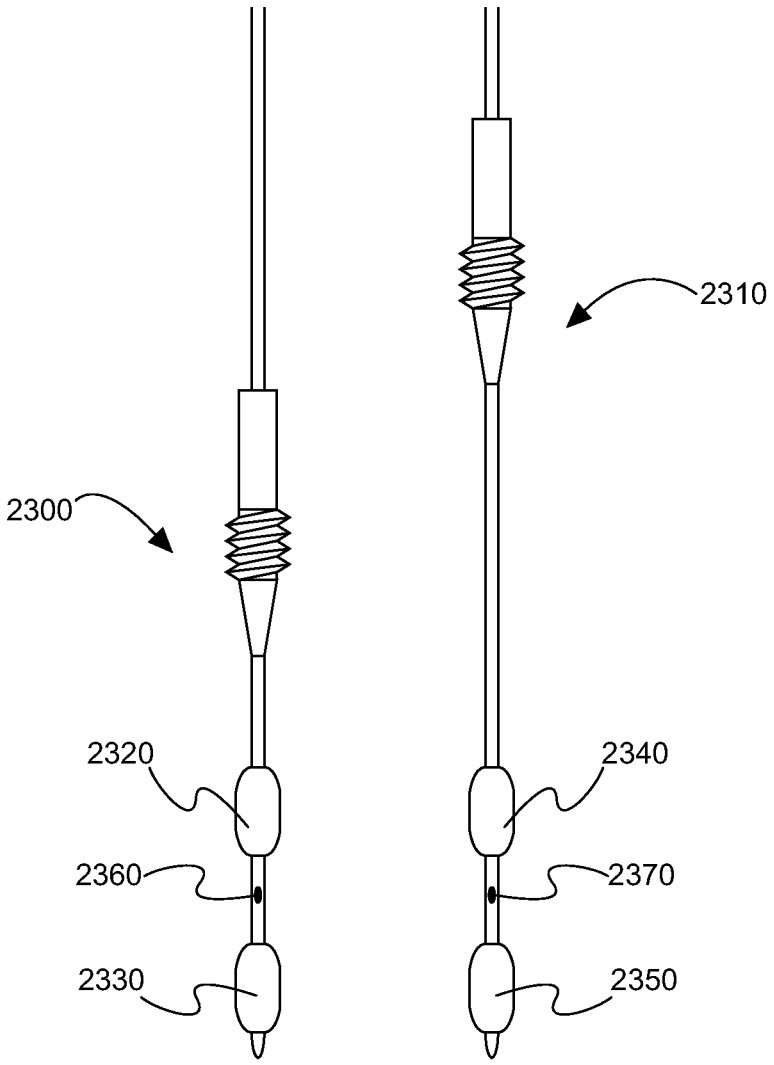

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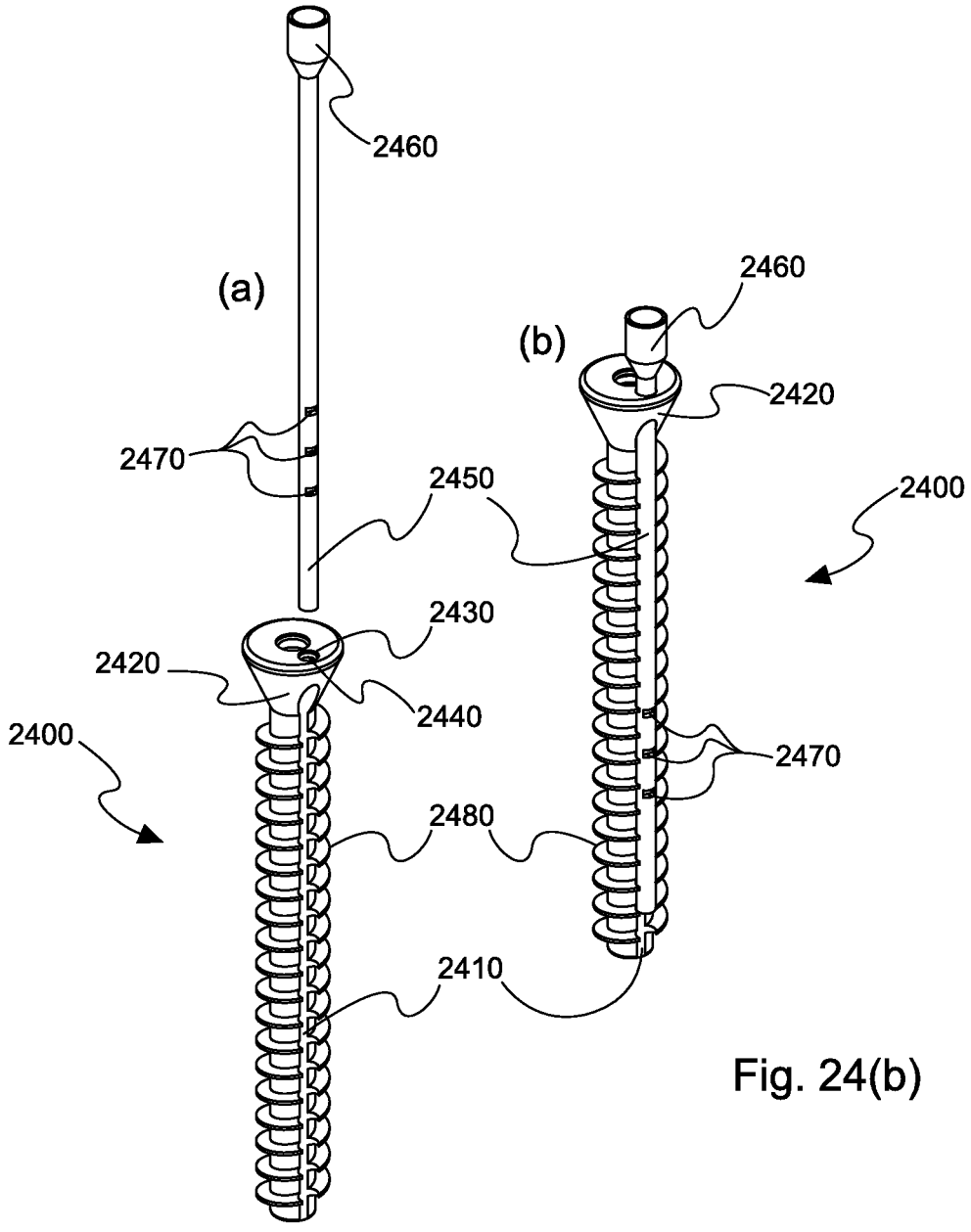
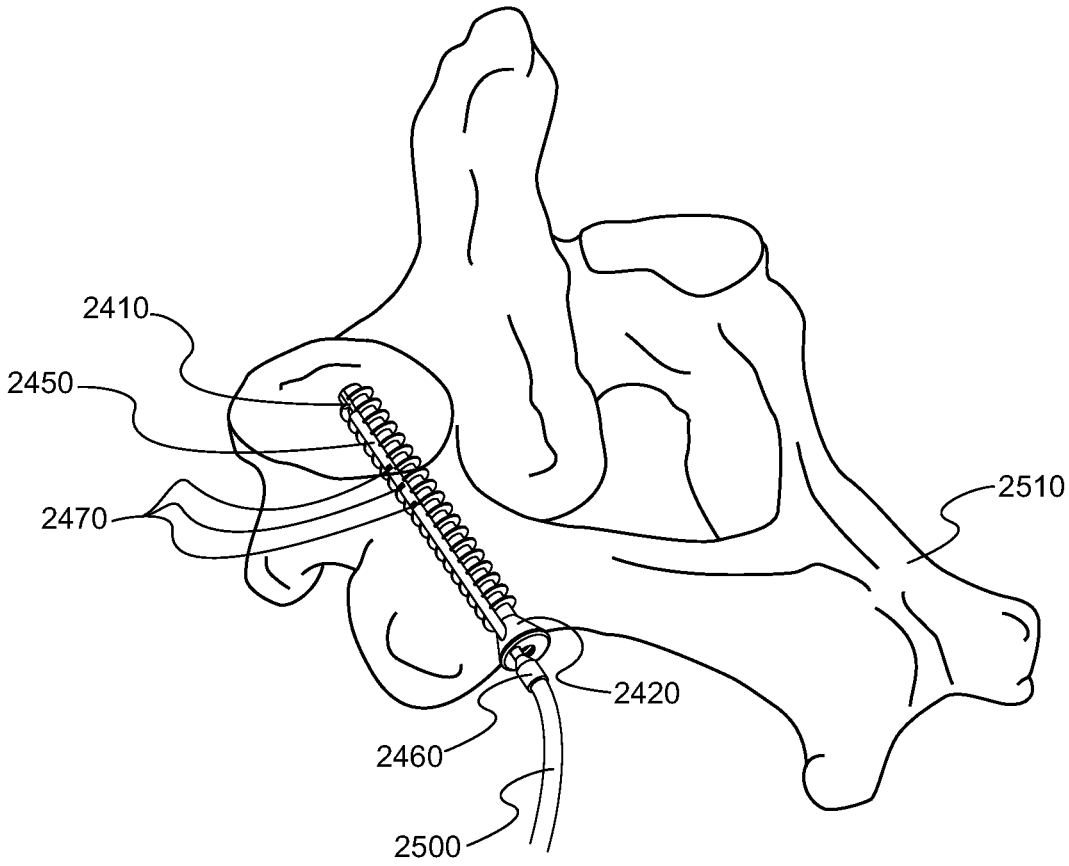


Fig. 24(b)

Fig. 24(a)



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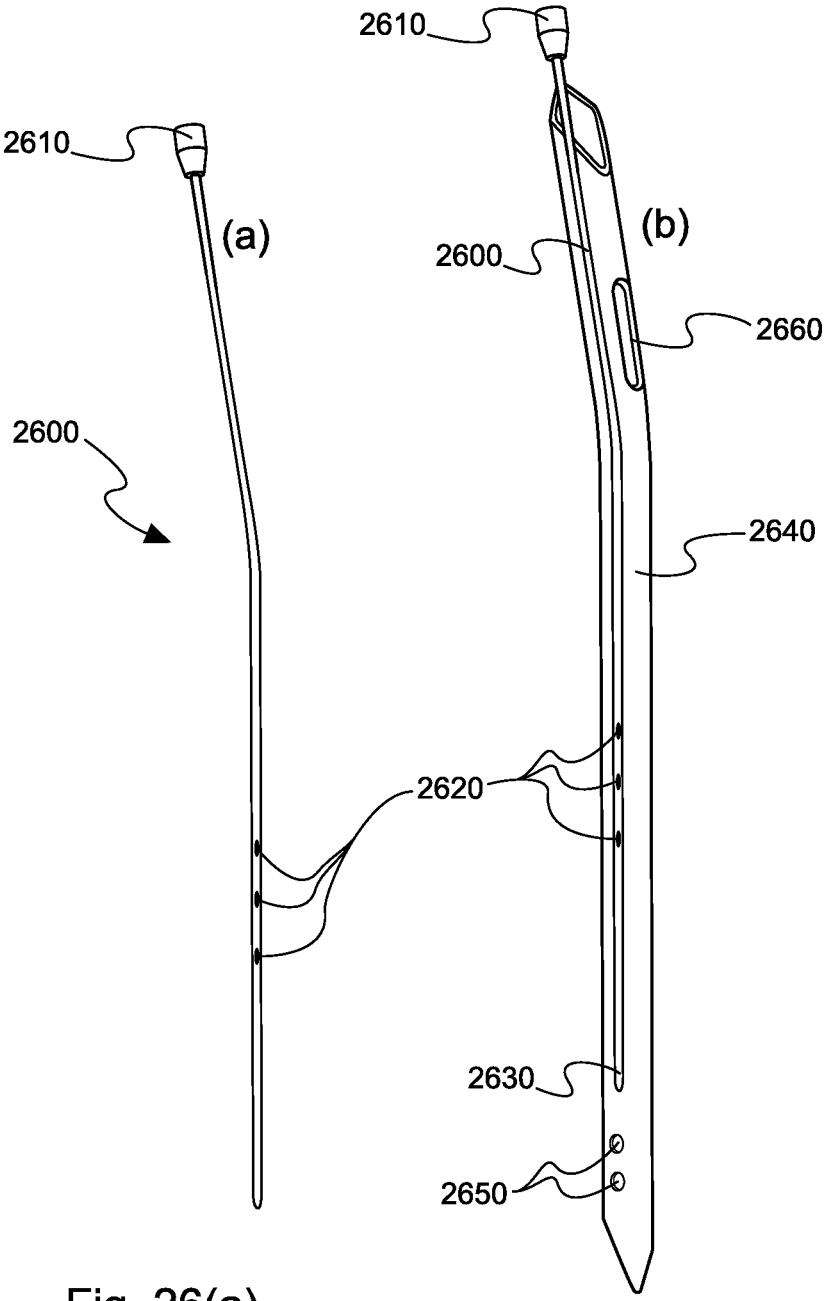
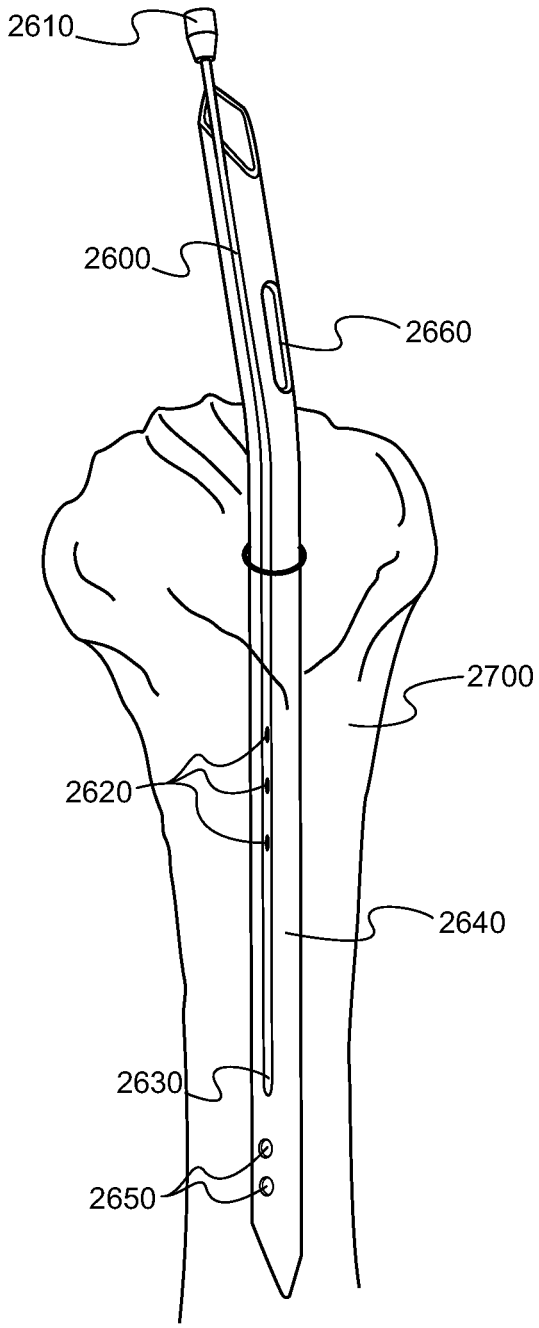


Fig. 26(a)

Fig. 26(b)



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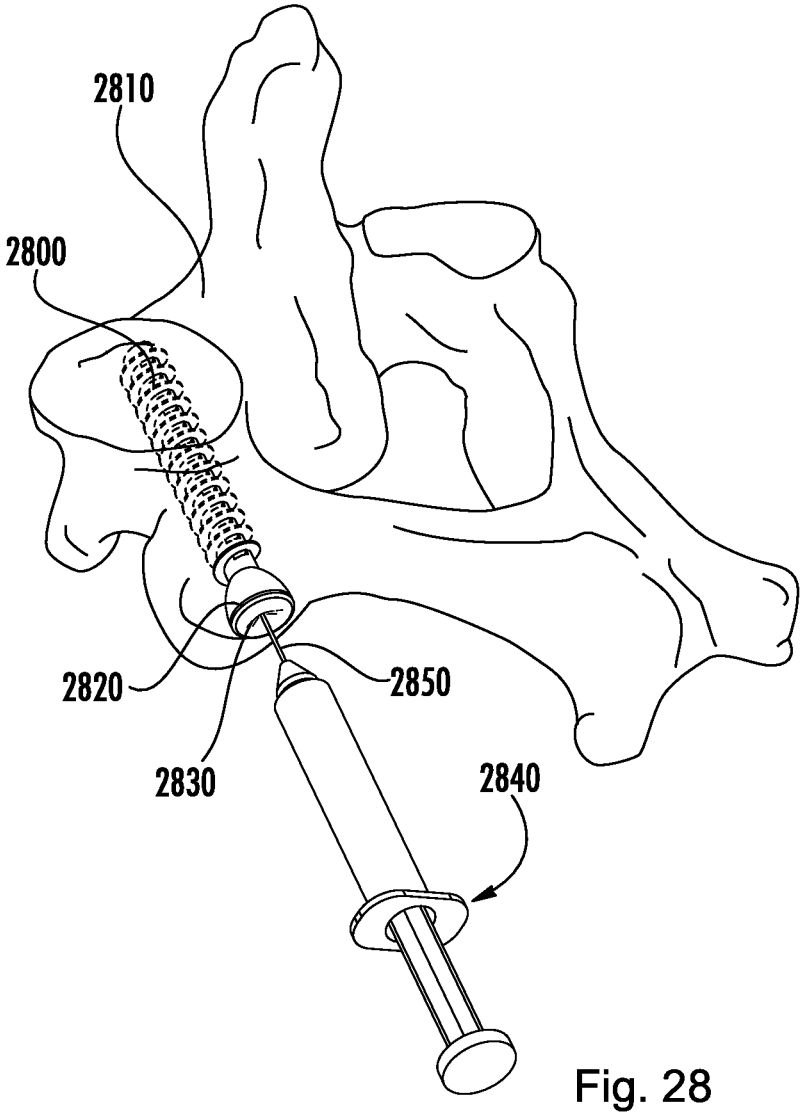

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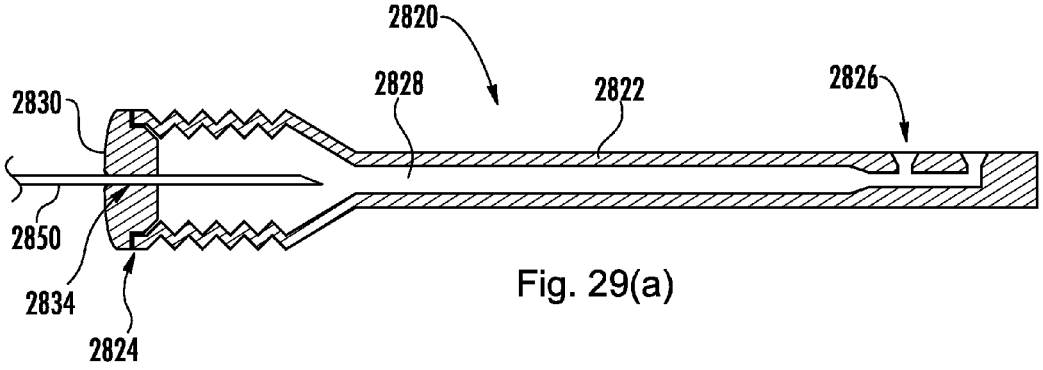
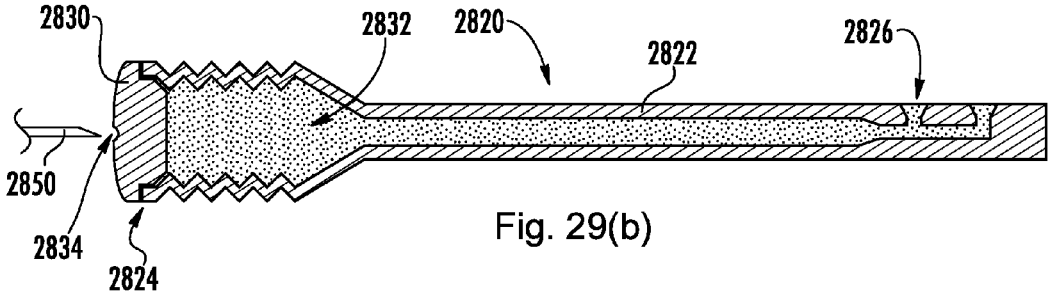


Fig. 29(a)



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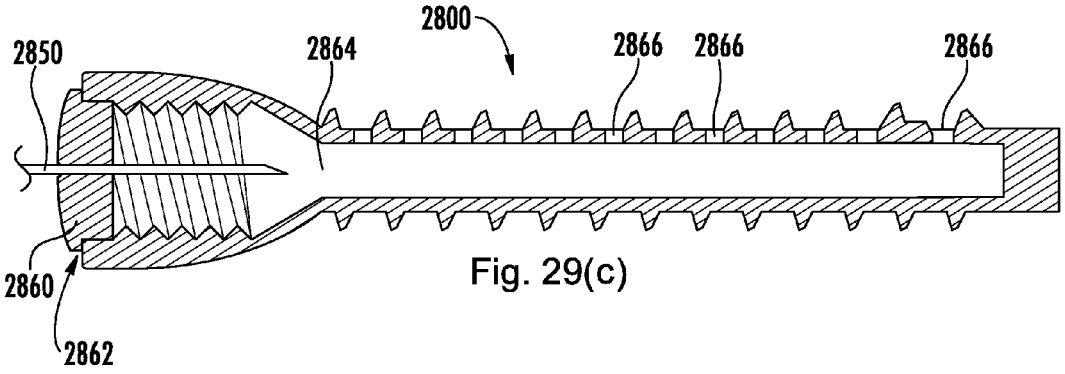

Fig. 29(c)

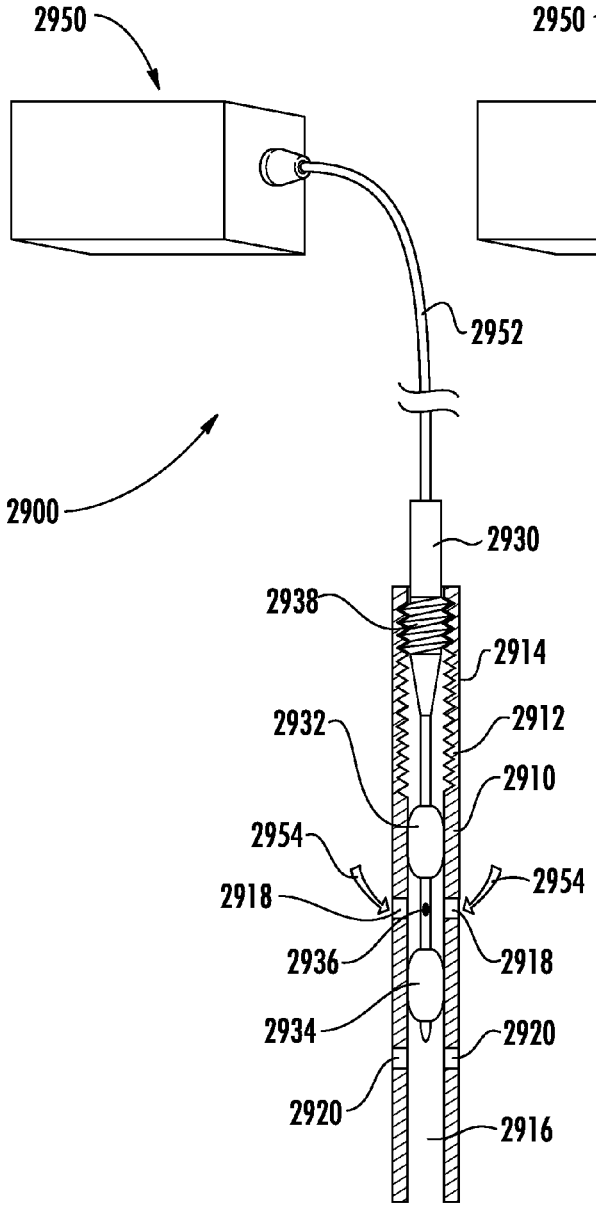

Fig. 30(a)

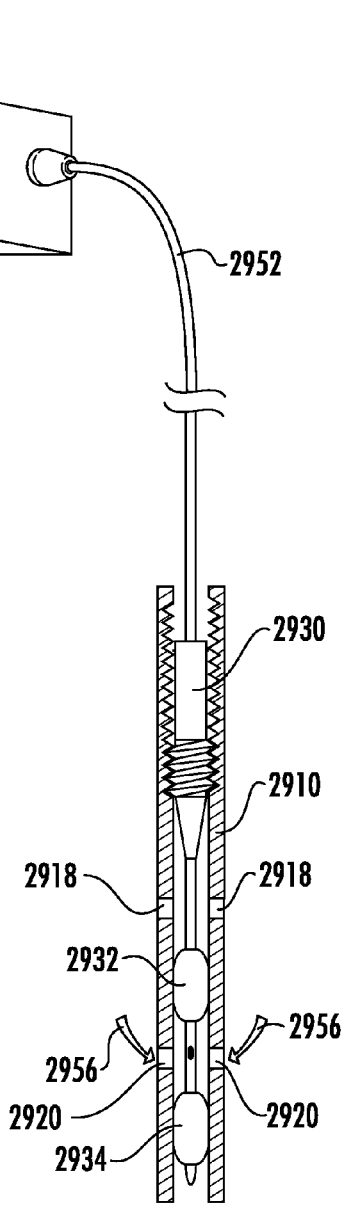

Fig. 30(b)

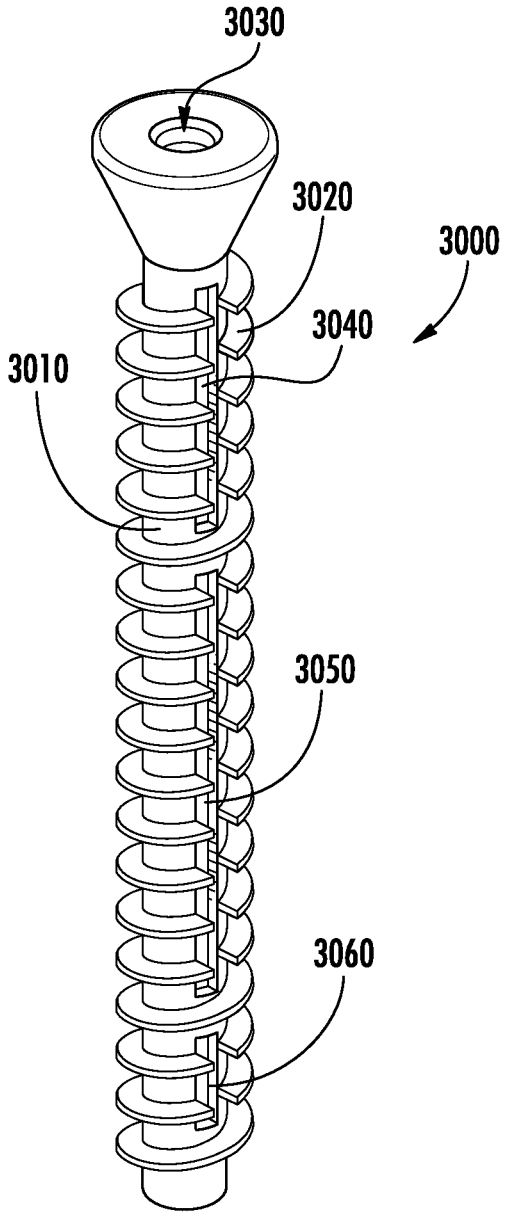

Fig. 31

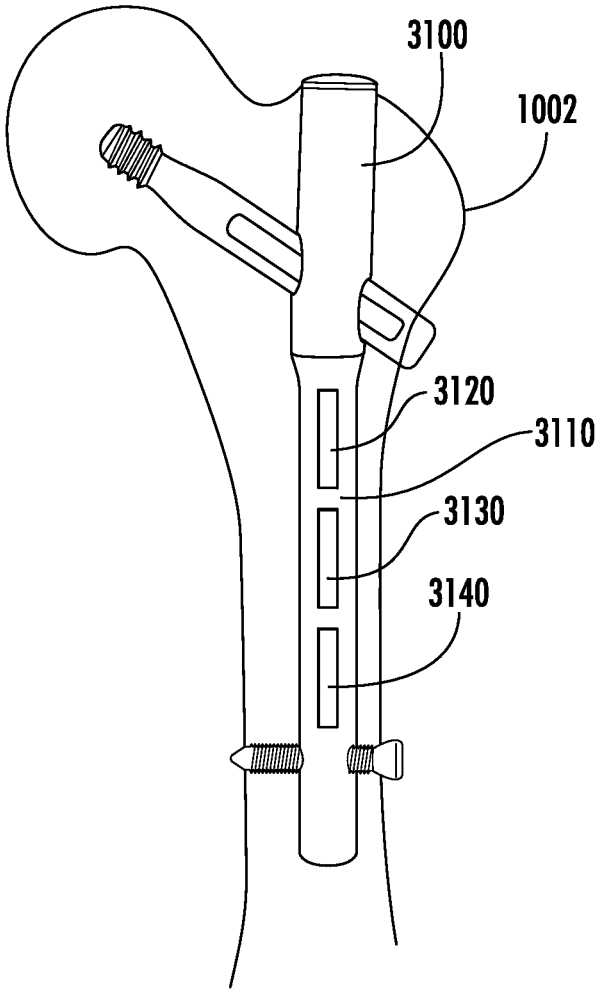

Fig. 32

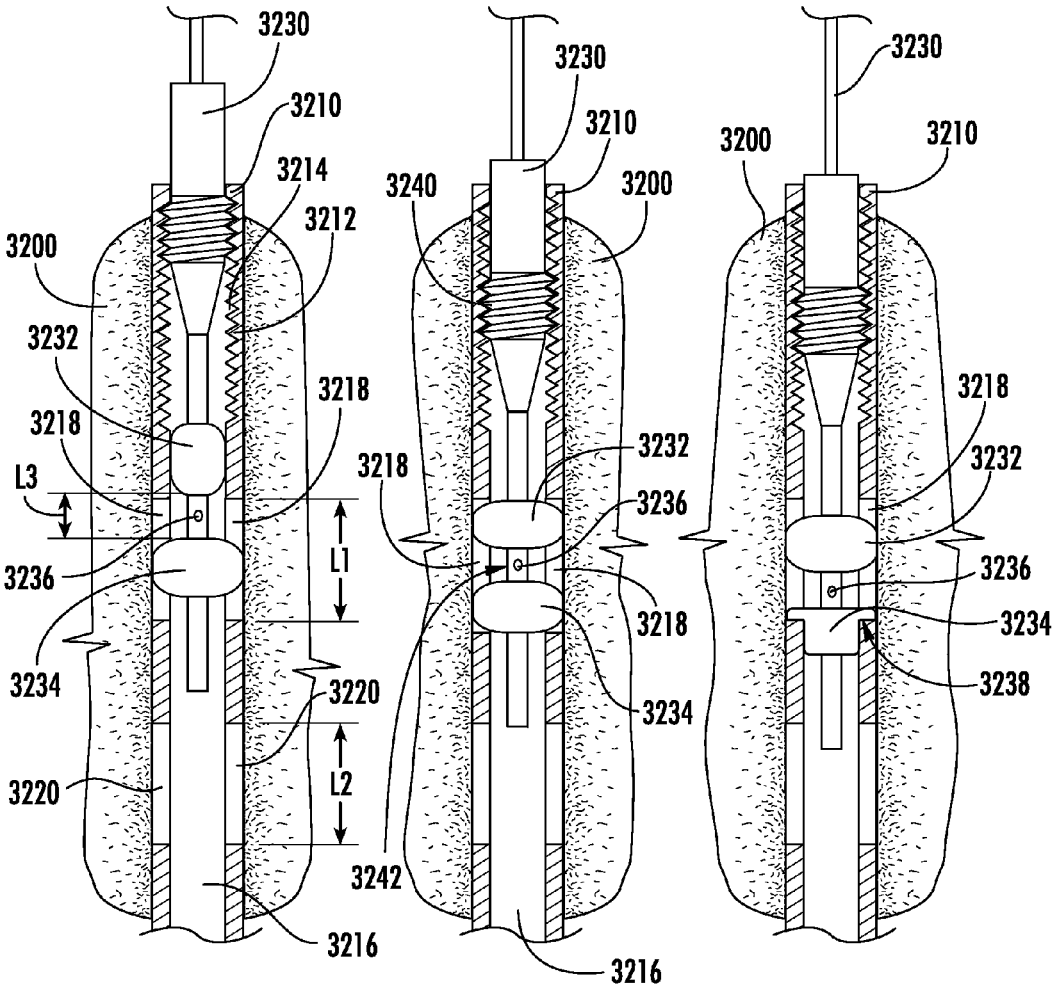

Fig. 33(a) Fig. 33(b) Fig. 33(c)

METHOD AND DEVICE FOR DELIVERING MEDICINE TO BONE

CROSS-REFERENCES TO RELATED APPLICATIONS

This application is a continuation of U.S. application Ser. No. 12/822,022, filed Jun. 23, 2010, which is a continuation-in-part of U.S. application Ser. No. 12/427,520, filed Apr. 21, 2009, which is a continuation of U.S. application Ser. No. 10/704,526, filed Nov. 7, 2003, which is a continuation-in-part of U.S. application Ser. No. 10/682,307, filed Oct. 9, 2003, and a continuation-in-part of U.S. application Ser. No. 10/620,287, filed Jul. 15, 2003. U.S. application Ser. Nos. 12/822,022, 12/427,520, 10/704,526, 10/682,307, and 10/620,287 are incorporated herein by reference in their entireties.

FIELD OF THE INVENTION

The present invention relates to devices and methods for delivering substances such as medicants to bones and to devices for removing materials from the body. More particularly, the present invention concerns devices and methods for delivering substances to the interior or exterior of fractured or otherwise injured bones, especially to the fracture interface thereof. The present invention also relates to devices and methods for removing materials from the interior or exterior of injured bone. The devices may also be used to promote fusion of a bone or a joint, including a peripheral joint such as a finger or a knee.

BACKGROUND OF THE INVENTION

Delivery of medicants or therapeutics to bones is an often desirable but difficult-to-achieve process, especially if one desires to focus the delivery to the interior of a bone or to a particular area in a bone. Delivery pins or needles, such as those disclosed in U.S. Pat. No. 6,210,376, the disclosure of which is hereby incorporated by reference herein, are sometimes used to deliver medication or other fluids into bone. Such pins are typically made of metals such as titanium or steel, and must be fabricated ahead of time for later use. Thus, it is difficult to customize the pins for directing the delivery of medicants or fluids to a specific area of interest within a bone. Moreover, such pins do not serve as fixation screws for holding two or more bones or bone pieces in a fixed spatial relationship with respect to each other.

Bone screws can be used to repair or strengthen fractured or otherwise damaged or diseased bones, often by fixing two or more bones or bone pieces with respect to each other, in which case the bone screw may be referred to as a fixation screw. Such screws have been adapted to deliver liquids such as bone cements to the interior of a bone, and are disclosed in U.S. Pat. Nos. 5,047,030 and 6,214,012, for example, the disclosures of which are hereby incorporated by reference herein. These devices must be fabricated ahead of time for later use, thereby substantially limiting the ability to customize the device to the needs of an individual patient. Moreover, while these devices may be suitable for the one-time delivery of a curable substance such as a bone cement, they provide no way to control or regulate the amount of substance delivered. Substance delivery also cannot be directed to certain areas within the bone and not others without changing the location or configuration of the bone screw itself. Thus, a need exists for a device capable of delivering a substance to a bone, especially to specific areas within the bone, such as a fracture interface. In addition, a further need exists for the ability to customize the delivery location and amount during the course of an operation, once the bone screw is in place, for example.

SUMMARY OF THE INVENTION

In accordance with the present invention, a bone-screw insert is disposed within or along a bone screw to provide a device for the delivery of a desired substance to the interior or exterior of a bone or its surrounding tissues.

In some embodiments, the bone screws and the inserts are cannulated along at least a portion of their lengths. The bone screws are fenestrated and the inserts are either fenestrated or permeable to the substance to be delivered such that when the insert is disposed within the bone screw a delivery pathway exists whereby the substance can be delivered from one end of the insert to the exterior of the bone screw through the bone-screw fenestrations. The bone-screw inserts of the present invention thus allow one to selectively block the bone-screw fenestrations to which substance delivery is not desired, while maintaining a substance delivery pathway to one or more bone-screw fenestrations to which substance delivery is desired.

In other embodiments, inserts, which may be fenestrated or permeable, are disposed along at least a portion of an exterior surface of the bone screws. In these designs, the inserts may be connected to the exterior surface of the bone screws using a variety of attachment means, including but not limited to, grooves, hooks, loops, and the like. For example, the bone screws may have one or more exterior grooves running along at least a portion of their lengths and the inserts may be adapted to fit into the grooves. The inserts may be either fenestrated or permeable to the substance to be delivered such that when the insert is disposed along the exterior surface of the screw a delivery pathway exists whereby the substance can be delivered from one end of the insert to the exterior of the bone screw through permeable insert walls or insert fenestrations.

In one aspect of the present invention the bone screw comprises a fixation screw whereby two or more bones or bone pieces may be held in a fixed spatial relationship with respect to each other. It may often be desirable to deliver a substance at or near the fracture interface of a broken bone, for example. In such a case, the desired positions of bone-screw fenestrations which will align with or match this location may not be known until after the bone screw has been disposed within the bone. The bone-screw inserts of the present invention thus allow one to tailor a substance delivery pathway through one or more insert and/or bone-screw fenestrations after the bone screw has been disposed within a bone.

In another aspect of the invention, the device comprises a reservoir which may serve as a source of the one or more substances to be delivered to the vicinity of a bone. Reservoirs useful in the practice of this invention may comprise the cannulated portions of the bone screw or insert, or they may be reservoirs that are connected to the bone screw or insert for substance delivery. In certain embodiments the present invention may further comprise a pump for facilitating the delivery of the one or more substances to the vicinity of a bone. Such pumps may, for example, aid in the continuous or regulated flow of a fluid into the bone screw or insert for delivery to the desired location.

Yet another aspect of the invention provides methods for administering a substance to a bone. In one embodiment, a method comprises introducing a cannulated, fenestrated

bone screw into a bone, introducing a cannulated insert into the bone screw cannulation, and introducing a substance to be delivered into the cannulated portion of the insert. In another embodiment, a method comprises attaching a cannulated insert along at least a portion of an exterior surface of a bone screw, introducing the bone screw into a bone, and introducing a substance to be delivered into the cannulated portion of the insert. The methods may comprise the use of a fenestrated or permeable insert, or the use of reservoirs or pumps to aid in substance delivery. In certain embodiments of the invention the insert may initially serve the purpose of preventing bone fragments, blood, fat, or other materials from entering the cannulated portion of the bone screw, especially during insertion of the bone screw into the bone, for example. This may then be followed by readjustment or realignment of the insert to provide a pathway for the substance to be delivered at a later point in time.

Another embodiment of the invention relates to a device for implantation within a bone. The device includes a first end, a second end and a shaft connecting the first and second ends. The shaft defines a cannulation extending along at least a portion of the length of the shaft. The device also includes a seal coupled to the shaft, the seal having an inner surface facing the cannulation of the shaft. The seal is configured to provide access to the cannulation following implantation of the device within the bone, and the seal is configured to self-seal after access is provided to the cannulation.

Another embodiment of the invention relates to a system for removing a substance from a bone. The system includes an insert having two ends connected by a shaft, and the shaft of the insert is cannulated along at least a portion of its length. The system includes an insert fenestration disposed along the cannulated portion of the insert. The system includes a bone screw having two ends connected by a shaft, and the bone screw is adapted to receive the insert. The system includes a device coupled to the insert and in communication with the cannulated portion of the insert, and the device is configured to draw material from the bone through the insert fenestration into the insert.

Another embodiment of the invention relates to a method for removing a substance from a bone. The method includes introducing a bone screw into the bone. The bone screw has two ends connected by a shaft and a portion adapted to be attached to an insert. The method includes attaching the insert to the bone screw. The insert has two ends connected by a shaft, and the shaft of the insert is cannulated along at least a portion of its length. The insert includes an insert fenestration disposed along the cannulated portion of the insert. The method includes coupling a device to the insert in communication with the cannulated portion of the insert, and removing material from the bone through the insert fenestration via the device.

Another embodiment of the invention relates to a system for treating a bone, which includes an insert for a bone screw or a fixation nail. The insert includes a shaft that extends between proximal and distal ends of the insert and a cap. The shaft includes an opening in the proximal end and a cannulation extending from the opening through at least a portion of the shaft. The shaft further includes a fenestration disposed along the cannulation such that the cannulation is configured to provide a pathway for a substance between the opening and the fenestration. The cap is fastened to and seals the opening in the proximal end of the shaft and adjoins the cannulation. The cap is configured to provide a needle access through the cap to the cannulation following implantation of the system within the bone, and is further configured to self-seal after the needle is removed.

Another embodiment of the invention relates to a system for removing material from a bone, which includes an insert, a bone screw, and an expandable portion. The insert includes a shaft extending between proximal and distal ends of the insert, a cannulation extending through at least a portion of the length of the shaft, and a fenestration disposed along the shaft and connecting to the cannulation. The bone screw includes a shaft extending between first and second ends of the bone screw. The shaft of the bone screw is cannulated. Furthermore, the bone screw is configured to receive the insert in the cannulation of the bone screw. The expandable portion is coupled to the insert and extends laterally from the insert to contact an interior surface of the cannulation of the bone screw, which forms a seal extending between the exterior of the insert and the interior of bone screw in the cannulated portion of the bone screw.

Another embodiment of the invention relates to a system for treating a bone, which includes a fastener and an insert. The fastener includes a rigid shaft extending lengthwise between first and second ends of the fastener. The first end includes an opening, and the shaft of the fastener includes a cannulation extending from the opening to the second end of the fastener. The fastener is fenestrated with an elongate slot extending lengthwise along the shaft. The insert includes a shaft extending between proximal and distal ends of the insert, a conduit extending from the proximal end and through at least a portion of the shaft, and a fenestration disposed along the shaft and connecting to the conduit. The insert is configured to be inserted through the opening in the first end of the fastener and is movable within the cannulation of the fastener.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** shows a perspective view of a bone screw in accordance with the present invention.

FIG. **2** shows a bone screw inserted into the hip bone of a patient.

FIG. **3**(*a*) shows a schematic cross-sectional view of a bone-screw insert with a single fenestration.

FIG. **3**(*b*) shows a perspective view of the bone-screw insert of FIG. **3**(*a*).

FIG. **4** shows a perspective view of a bone screw, a bone-screw insert, and an insert cap, in accordance with the present invention.

FIG. **5**(*a*) shows a schematic cross-sectional view of a bone-screw insert with multiple fenestrations.

FIG. **5**(*b*) shows a perspective view of the bone-screw insert of FIG. **5**(*a*).

FIG. **6** shows a schematic cross-sectional view of a bone-screw insert with a porous section along the length of the shaft.

FIG. **7** shows a schematic cross-sectional view of a bone-screw insert with an internal reservoir and a cap.

FIG. **8**(*a*) shows a perspective view of a syringe being used to provide a liquid to a bone screw disposed in a hip bone.

FIG. **8**(*b*) shows a perspective view of a IV being used to provide a liquid to a bone screw disposed in a hip bone.

FIG. **9** shows a perspective view of a pump assembly being used to provide a liquid to a bone screw disposed in a hip bone.

FIG. **10** shows a fixation nail inserted into the femur bone of a patient.

FIG. **11** shows a cross-sectional view of the fixation nail of FIG. **10**.

FIG. **12** shows a perspective view of a bone-screw insert being inserted into the fixation nail of FIG. **10**.

FIG. **13** shows a fixation nail inserted into the humerus bone of a patient.

FIG. **14** shows a cross-sectional view of the fixation nail of FIG. **13**.

FIG. **15** shows a perspective view of a bone-screw insert being inserted into the fixation nail of FIG. **13**.

FIG. **16** shows a fixation nail inserted into the tibia bone of a patient.

FIG. **17** shows a cross-sectional view of the fixation nail of FIG. **16**.

FIG. **18** shows a perspective view of the fixation nail of FIG. **16**.

FIG. **19** shows a perspective view of an IV being used to provide a liquid to the fixation nail of FIG. **16**.

FIG. **20** shows a perspective view of a pump assembly being used to provide a liquid to the fixation nail of FIG. **16**.

FIG. **21** shows an insert having deflated balloons along its length being inserted into a bone screw.

FIG. **22** shows the insert of FIG. **21** with inflated balloons disposed inside the bone screw.

FIG. **23** shows two inserts of different lengths having balloons disposed around their shafts.

FIG. **24**(*a*) shows a perspective view of a bone screw having and external groove along its length and a fenestrated insert adapted to fit into the groove.

FIG. **24**(*b*) shows a perspective view of the insert of FIG. **24**(*a*) inserted into the groove along the bone screw of FIG. **24**(*a*).

FIG. **25** shows the bone screw and insert of FIG. **24**(*b*) inserted into the hip bone of a patient.

FIG. **26**(*a*) shows a perspective view of an insert adapted to fit into a groove along fixation nail.

FIG. **26**(*b*) shows a perspective view of the insert of FIG. **26**(*a*) inserted in a groove running along the length of a fixation nail.

FIG. **27** shows the fixation nail and insert of FIG. **26**(*b*) inserted into the tibia bone of a patient.

FIG. **28** shows a bone screw and an insert disposed in a bone and a perspective view of a syringe being used to provide a substance to the bone screw, according to an exemplary embodiment.

FIG. **29**(*a*) shows a schematic cross-sectional view of a bone-screw insert with a resealing cap, according to an exemplary embodiment.

FIG. **29**(*b*) shows a schematic cross-sectional view of the bone-screw insert of FIG. **29**(*a*) following delivery of a substance to the insert.

FIG. **29**(*c*) shows a schematic cross-sectional view of a bone screw with a resealing cap, according to an exemplary embodiment.

FIG. **30**(*a*) shows a schematic cross-sectional view of an insert as part of a material removal system, according to an exemplary embodiment.

FIG. **30**(*b*) shows the material removal system of FIG. **30**(*a*) with the insert in a second position, according to an exemplary embodiment.

FIG. **31** shows a perspective view of a bone screw including slot-shaped fenestrations, according to an exemplary embodiment.

FIG. **32** shows a fixation nail including slot-shaped fenestrations inserted into the femur bone of a patient, according to an exemplary embodiment.

FIG. **33**(*a*) shows a schematic cross-sectional view of an insert disposed in a first position within a bone screw, according to an exemplary embodiment.

FIG. **33**(*b*) shows a schematic cross-sectional view of the insert of FIG. **33**(*a*) disposed in a second position within a bone screw, according to an exemplary embodiment.

FIG. **33**(*c*) shows a schematic cross-sectional view of the insert of FIG. **33**(*a*) disposed in a third position within a bone screw, according to an exemplary embodiment.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

In accordance with the present invention, a bone-screw-insert is disposed within a fenestrated bone screw or along an external surface of a bone screw, and the combination is used to deliver desired substances to the vicinity of a bone. The inserts are cannulated along at least a portion of their lengths and the bone screws may have an internal cannulation and/or one or more exterior insert attachment mechanisms running along at least a portion of their lengths. In certain embodiments, the insert may also be fenestrated or permeable to the substance to be delivered. The inserts of the present invention may be comprised of a single piece, or alternatively the insert may be comprised of several pieces or sections. In certain embodiments, the bone screw may be a fixation screw used to hold two or more bones or bone pieces in a fixed spatial relationship with respect to each other. The substances to be delivered may comprise medicants or therapeutics, or other substances which are desirable to deliver to the vicinity of a bone. The substance or a combination of substances may be delivered to the interior of a bone, to the exterior of a bone, to the fracture interface between two or more broken bones, or to any other location which may be facilitated by utilization of the present invention.

For the purposes of this invention, the term "cannulated" means that the screw or insert comprises a hollow cavity disposed inside at least part of its shaft. For example, the cavity may consist of a bore beginning at or near one end of the screw or insert and extending longitudinally into the screw or insert. Other configurations are possible, however, and the hollow cavity need not be restricted to a cylindrical shape or a circular cross-section. The cavity may extend throughout the entire length of the screw or insert, thus creating openings at each end of the screw or insert, or alternatively, the cavity may extend only partially into the interior of the screw or insert. The shape and size of the cavity may be suitably chosen to allow delivery of the desired substance through the screw or insert to the bone area of interest. When it is desired to use the cannulated portion of the screw or insert as reservoir for the substance to be delivered, for example, the cavity may be made as large as possible so long as the screw and insert maintain the structural integrity needed for introduction into the bone.

For the purposes of this invention, the term "fenestration" is used broadly to include any slot, gap, or perforation that defines an opening between the inside of the cannulated portion of the screw or insert to the outside of the screw or insert whereby a desired substance may be delivered. Thus, a fenestrated screw comprises an opening which defines a substance delivery pathway between the internal cannulated portion and the exterior of the screw. Likewise, a fenestrated insert is one that comprises an opening which defines a substance delivery pathway between the internal cannulated portion and the exterior of the insert. In certain embodiments of the present invention where a fenestrated insert is utilized

in combination with a fenestrated screw, at least one screw fenestration and at least one insert fenestration may be designed to align with each other once the screw and insert are in their appropriate configuration and position. Alignment or coordination of an insert fenestration and a screw fenestration will define a substance delivery pathway between the internal cannulated portion of the insert and the exterior of the screw.

In accordance with the present invention, fenestrations will typically extend in the radial direction from the internal cannulation to the exterior of the screw or insert, but other configurations are possible. Such fenestrations are separate and distinct from the opening at or near the one end of the screw or insert created by the cannulation. Further in accordance with the present invention, the fenestrations may be any desired shape or size desired to effect the delivery of the desired substance. For example, the fenestration cross-sections may be round, oval, or square. The fenestration cross-sections may, if desired, change shape between the inside and the outside of the screw or insert. Any number or combination of fenestrations may be located along the shaft or at the ends of the screws and inserts of the present invention. The insert fenestrations may be larger or smaller than the screw fenestrations.

An insert may have an outside diameter large enough such that the outside of the insert is pressed snuggly against the inside of the cannulation when the insert is in a bone screw in order to prevent the substance to be delivered from leaking between the insert and the bone screw and escaping through a bone screw fenestration from which it was not intended to escape. Alternatively, the insert may include one or more balloons along its length. These balloons, each of which is disposed around a portion of the insert, may be deflated when the insert is placed into the bone screw and subsequently inflated. Upon inflation, each balloon forms a seal between the outside of the insert and the inside of the bone screw. Using this construction, one or more insert fenestrations and one or more bone screw fenestrations may be isolated between two inflated balloons, such that a substance delivered through the isolated insert fenestrations may exit only through bone screw fenestrations positioned between the inflated balloons. Inserts having different lengths and/or different balloon placements may be provided such that the appropriate insert and bone screw fenestrations may be isolated to provide an appropriate delivery pathway depending on the final position of the bone screw in a patient relative to the desired delivery location.

As an alternative to or in combination with an insert disposed within an internal cannulation in a bone screw, the devices provided herein may include an insert disposed along an exterior surface of a bone screw. Again, the insert may be cannulated and fenestrated or permeable to define a delivery pathway between one end of the cannulation and a portion of a bone. In this embodiment, a bone screw is provided with a means for securing an insert along at least a portion of an exterior surface of the bone screw. For example, the bone screw may include at least one groove, adapted to accept an insert, running along at least a portion of its exterior surface. Alternatively, the bone screw may include one or more attachment mechanisms, such as loops, hooks or the like, along at least a portion of its exterior surface. An insert may be inserted through these loops or hooks, securing the insert to the bone screw. In order to ensure that the attachment elements do not interfere with the insertion of the bone screw into the bone, they are desirably set back from the external circumferential surface of the bone screw. If the bone screw includes threads, the attachment elements desirably do not extend radially beyond the threads. The bone screws may be adapted to secure two or more inserts along their exterior surfaces. This design allows the physician to select the appropriate number and placement for the inserts, depending on the final positioning of the bone screw in a bone.

In some embodiments, a cannulated, fenestrated bone screw may be combined with an exterior insert to provide a delivery pathway between the bone-screw cannulation and the exterior of the bone screw. In this embodiment, an insert is disposed along an external surface of the bone screw and may be used to selectively cover one or more bone-screw fenestrations in order to provide a substance delivery pathway that is appropriate based on the positioning of the bone screw in a bone. For example, a delivery device may include a cannulated bone screw having an exterior groove running along at least a portion of its length and an insert adapted to slide into the groove. Fenestrations are disposed along the groove of the bone screw to allow a substance to pass from the cannulation to the exterior of the bone screw. When a chosen insert is inserted into the groove, it selectively covers those fenestrations that provide a delivery pathway to areas of the bone where delivery of the substance is not needed, while leaving unblocked those fenestrations that provide a delivery pathway to areas of the bone where delivery of the substance is desirable.

For the purposes of this invention, the term "bone screw" is intended to refer to screws of all types which are presently known or hereafter devised for implantation into bone. In this regard, cancellous screws, cortical screws, and machine screws are all contemplated as being within the scope of the types of screws useful in the practice of the present invention. The bone screws of the present invention will typically comprise threads along at least a portion of the exterior of the screw shaft, but it should be appreciated that tacks, pins, nails and the like may also be included within the definition of a bone screw for the purposes of the present invention, whether threaded or unthreaded. When threads are present, it may be found advantageous to use self-tapping threads, or alternatively, the threads can be pre-cut in the bone prior to bone-screw insertion.

Referring now to FIG. **1**, there is disclosed a bone screw **100** having two ends **102** and **104** connected by a shaft **106**, and bone screw threads **110**. The cut-out of FIG. **1** reveals that bone screw **100** comprises a cannulated portion **120**, and bone screw fenestrations **130** along the length of the cannulated portion **120**. It will be appreciated by one skilled in the art that the fenestrations **130** need not be even spaced along the cannulated portion **120**, but may be arranged in a desired pattern or frequency along the length of the cannulated portion **120**. It will be further appreciated by one skilled in the art that one end **122** of the cannulated portion **120** of the bone screw **100** is configured to accept a bone screw insert. For example, the bone screw **100** may comprise additional threads **140** on the one end **122** of the cannulated portion **120** to promote fixation of a bone screw insert.

In one embodiment of the current invention the bone screw may be a fixation screw used to hold two or more bones or bone pieces in a fixed spatial relationship with respect to each other. Fixation screws are known in the art. One such device is disclosed by Tronzo, U.S. Pat. No. 4,653,489, the disclosure of which is hereby incorporated by reference herein. In accordance with the present invention, the bone screw may be used to mend peripheral skeletal fractures or osteotomies, repair a spondyloysis or an odontoid fracture, or fuse lumbar facet joints, for example. Other

beneficial uses of bone screws, and more particularly, fixation screws, will be known to one skilled in the art and are to be included within the scope of the present invention.

Referring now to FIG. **2**, there is disclosed a bone screw **100** disposed partially within a bone **200**. Bone **200** may, for example, represent a human hip bone. In one embodiment, bone screw **100** is disposed within bone **200** by rotating the bone screw **100** such that the bone screw threads **110** act to pull bone screw **100** into bone **200**, thereby anchoring bone screw **100** into place.

Bone screws of the present invention may comprise any material suitable for placement into a bone without harmful effects on the patient. Examples of suitable materials include, but are not limited to, titanium and its alloys, tantalum and its alloys, nickel-cadmium and its alloys, steel and its alloys, plastics, absorbable materials, resorbable materials, polyamino acids, polylactide, polyglycolide, hydroxylapatite, and tricalciumphosphate. Other materials useful for bone screw construction will be known to those skilled in the art, and are to be included within the scope of the present invention.

The device of the present invention further comprises a bone-screw insert. For the purposes of this invention, the term "insert" is used to refer to one or more cannulated members which are disposed within the cannulated portion of a bone screw. Referring now to FIG. **3**(*a*), the insert **300** comprises a cannulated portion **310** which consists of a hollow cavity **320** surrounded by the insert wall **330**, where the cavity and wall dimensions may be suitably chosen in order to carry out the practice of the invention disclosed herewith. In certain embodiments, the insert may comprise a single piece, as disclosed in FIG. **3**(*a*). Alternatively, the insert may comprise two or more pieces or sections that, when taken together, form the insert of the present invention. Referring now to FIG. **3**(*b*), when the insert **300** is a single piece, the insert comprises two ends, **302** and **304**, connected by a shaft **306**. The shaft may be cannulated along its entire length, creating openings at each end of the insert. Alternatively, the cannulation may extend only partially into the shaft so long as the cannulation is sufficient to allow for delivery of a substance from one end of the insert to one or more bone-screw fenestrations. One end **302** of the insert **300** may comprise threads **340** which interlock with bone screw threads **140** of FIG. **1** to help fix an insert **300** into a bone screw **100**. When the insert comprises two or more pieces or sections, only one of the sections need be cannulated such that the insert sections, when taken together, allow for delivery of a substance from one end of the insert to one or more bone-screw fenestrations.

In one embodiment of the present invention, the exterior dimensions of the insert are only slightly smaller than the interior dimensions of a cannulated bone screw to provide for a tight but sliding fit when the insert is placed into the bone screw, as depicted in FIG. **4** in which an insert **400** is shown partially disposed within a bone screw **410**. Also disclosed in FIG. **4** is an insert cap **415** which can be used to substantially seal the one end **402** of the insert **400** via insert cap threads **420** either before, during, or after the bone screw **410** and insert **400** are put into place. The insert may have substantially the same cross-sectional shape as the cannulated portion of the bone screw, or their cross-sectional shapes may be different. For example, the internal bone screw cavity and the exterior surface of the insert may have a substantially circular cross-section. One advantage of this embodiment is that after the insert has been disposed within the bone screw, the insert may be rotated with respect to the screw to achieve alignment of certain of the insert and bone-screw fenestrations, for example. In another embodiment, the insert and bone screw may have substantially non-circular cross-sections such that the insert is not free to rotate once it has been disposed within the bone screw. In yet another embodiment, at least part of the insert cross-section may not match that of the bone screw cavity such that when the insert is disposed within the bone screw, one or more channels are formed longitudinally along at least part of the insert and bone screw shafts. Such channels may be useful, for example, to allow air or fluids to escape the bone screw cavity as the insert is introduced.

When substantially unimpeded delivery of a substance to one or more bone-screw fenestrations is desired, the inserts of the present invention may comprise one or more insert fenestrations **510**, as depicted in FIG. **5**(*a*). An insert having an appropriate number, size, shape, and location of insert fenestrations can be chosen by the practitioner without undue experimentation to provide a delivery pathway between at least one end of the insert and the one or more bone-screw fenestrations. For example, FIG. **5**(*b*) discloses an insert **500** comprising a plurality of insert fenestrations **510** having a substantially rectangular cross-section. Alternatively, the delivery pathway may initiate at one end of the bone screw and pass through the insert to one or more bone-screw fenestrations. The insert fenestrations need not match the bone-screw fenestrations in number, size, shape, or location, although it may be advantageous to locate at least one of the insert fenestrations such that it may be substantially aligned with at least one bone-screw fenestrations once both the bone screw and the insert are in place.

In another embodiment of the present invention, the inserts of the present invention may be permeable to the substance to be delivered such that the substance is delivered to the exterior of the insert by diffusion through the insert wall or through small openings in the insert wall. Such openings may be intentionally created such as by increasing the porosity of the insert material (e.g., by introducing a series of pinpricks into the material), or they may exist naturally as pores in the material. Referring to FIG. **6**, there is disclosed an insert **600** comprising a cannulated portion **610** and a permeable material **620** wherein a substance to be delivered can travel from one end **602** of the insert to the permeable material **620**. When the insert comprises a material that is at least partially permeable to the substance to be delivered, the insert may or may not be fenestrated so long as delivery of the desired substance is not completely impeded by the insert. An embodiment of the present invention comprising a permeable but non-fenestrated insert may be preferred when it is desired to effect a controlled, slow release of the desired substance to a bone, or when it is desired to prevent bone fragments, blood, fat or other materials or fluids from traveling from the exterior of the insert to the interior cavity.

When it is desired to use the cannulated portion of the insert as a reservoir for the substance to be delivered, or when the substance is to be delivered to a bone by permeation through the insert walls, it may be desirable to make the insert walls as thin as possible. Referring now to FIG. **7**, there is disclosed an insert **700** with walls **710** surrounding a reservoir **720**. One end **702** of the insert may be substantially sealed by insert cap **715**. For example, in one embodiment, the insert may comprise a thin-walled tube which increases the available volume for storage of the substance, and which also increases the diffusion of the substance through the insert wall. In another embodiment, the insert may comprise a film or coating on the interior surfaces of the bone-screw cavity. Inserts in accordance with this embodi-

ment may be as thin as a few hundred nanometers or less, which again may be beneficial for increasing the reservoir size with the bone screw and insert cavity, and for increasing the diffusion of the substance through the insert wall.

In another aspect of the present invention, the delivery of a substance to a bone may alternately be controlled or directed by diminishing the cavity size within the insert so that the movement of the substance is restricted. In this embodiment, it may be desired that the insert cannulation or insert fenestrations be a few microns (e.g., 5 microns) or less in size. Referring again to FIG. **7**, there is further disclosed a cannulated portion **730** of insert **700** which is diminished in size so as to restrict or limit the flow of a substance from the reservoir **720**. The exact configuration and geometry of an insert providing the desired level of substance delivery can be determined by one skilled in the art without undue experimentation, and all such configurations are to be included within the scope of the present invention.

In yet another aspect of the present invention, the inserts may control or direct the delivery of a substance to a bone through a fenestrated bone screw by substantially blocking one or more of the bone-screw fenestrations. This approach may be advantageous when it is desired to deliver the substance to a specific location with respect to the bone screw's position within the bone. Since the exact bone-screw fenestrations which align with or match this location may not be known until after the bone screw has been disposed within the bone, the bone screw inserts of the present invention allow one to selectively block the bone-screw fenestrations to which substance delivery is not desired, while maintaining a substance delivery pathway to one or more bone-screw fenestrations to which substance delivery is desired. Moreover, by utilizing an insert whereby the insert fenestrations align with the bone-screw fenestrations to which substance delivery is desired, one may achieve substantially unimpeded delivery of the substance to the area of interest.

In addition, the bone-screw inserts of the present invention, even when fenestrated, may be advantageously used to significantly hinder bone fragments, blood, fat, or other materials from entering the cannulated portion of the bone screw, especially during insertion of the bone screw into the bone, for example. In this case it may be desirable to initially position the insert and bone screw such that the insert fenestrations do not align with the bone-screw fenestrations. The insert may then be subsequently re-positioned at a later time to align one or more of the insert fenestrations with the bone-screw fenestrations to facilitate substance delivery.

Inserts of the present invention may comprise any material compatible with the bone screw and able to be placed within the bone screw without producing adverse effects to the patient. Examples of suitable insert materials include, but are not limited to, titanium and its alloys, tantalum and its alloys, nickel-cadmium and its alloys, steel and its alloys, plastics, absorbable materials, resorbable materials, polyamino acids, polylactide, polyglycolide, hydroxylapatite, and tricalciumphosphate. Other materials useful for insert construction will be known to those skilled in the art, and are to be included within the scope of the present invention. When the insert comprises two or more sections, the sections need not comprise the same material. In addition, when it is desired that the insert be permeable to the substance to be delivered, one or more of the insert sections may comprise a material specifically chosen to impart the desired level of permeability to the insert.

The insert may be sold or otherwise provided in a kit containing two or more inserts having different fenestrations or permeability characteristics. The availability of such a kit has the advantage of allowing a practitioner to select an appropriate insert based on the particular needs of the patient.

In accordance with the present invention, the insert is disposed within the bone screw to provide for a directed or controlled delivery of a desired substance to a bone. For the purposes of this invention, the term "substance" is used to refer to one or more chemical compounds that are useful when delivered to the vicinity of a bone. Substances may be chosen to help treat diseased bone as well as fractured or otherwise injured bones. Alternatively, the substance may be delivered to otherwise healthy bone to help maintain overall bone health, for example. Representative example substances include medicants or therapeutics such as antibiotics, chemotherapeutics, angiogenic factors, bone morphogenic proteins, and bone growth factors. Other desirable substances may be known or hereinafter determined by one skilled in the art, which are to be included within the scope of this invention.

In certain applications of the present invention it may be desirable that the substance be stored in a reservoir prior to delivery to a bone. Thus, it may be advantageous for the device of the present invention to further comprise a reservoir. For the purposes of this invention, the term "reservoir" refers to any source of the one or more substances to be delivered to the vicinity of a bone. For example, the reservoir may comprise the hollow cavity created by the cannulation of the bone-screw insert and any part of the bone-screw cannulation not occupied by the insert, as depicted in FIG. **7** and described above. In one embodiment of the present invention, the substance to be delivered may be absorbed into a sponge-like material such as a collagen, for example, which may then be disposed within the cannulated portion of the bone screw or insert, or both. When additional reservoir space is desired, a suitable reservoir may be connected to the cannula opening of either the bone screw or insert. For example, FIG. **8**(*a*) discloses a bone screw **800** and an insert **810** disposed therein, both of which are disposed within a bone **820**. FIG. **8**(*a*) further discloses a syringe **830** which acts as a reservoir in accordance with the present invention to provide a substance to the bone **820** via bone screw **800** and insert **810**. Another embodiment of the present invention, is depicted in FIG. **8**(*b*) which discloses an IV **840** which serves as a reservoir for delivering a substance to a bone via a bone screw and an insert. In yet another embodiment of the present invention, the reservoir may be implanted beneath the patient's skin, i.e., subcutaneously.

In another aspect of the present invention, it may be advantageous for the device of the present invention to further include a pump **920**, as depicted in FIG. **9**, for delivering a substance to a bone via a bone screw and an insert **910**, and tubing **930**. A pump may be utilized to aid in delivery of the substance to the vicinity of a bone by, for example, delivering a continuous, regulated volume to the screw. The pump may also be used to increase the fluid pressure within the cannulated portion of the insert, thereby aiding fluid flow through the insert fenestrations or insert walls, for example. This embodiment may have the further advantage that the positive pressure created by the pump within the cannulated portion of the insert or bone screw hampers the influx of unwanted materials or compounds into the device. The pump may be connected to the cannulated portion of the bone screw or insert as depicted in FIG. **9**, and the pump may also be implanted subcutaneously if desired. Examples of pumps which may be suitably used in the

practice of the current invention are the implantable pumps disclosed in U.S. Pat. No. 4,588,394, for example. Other examples may be relatively simple pumps such as external pumps similar to those used with patient controlled anesthesia machines or simple IV pumps. These and other pump types and designs which may be currently known or hereinafter discerned by one skilled in the art are to be included within the scope of this invention.

In one embodiment of the invention the bone screw may be a fixation nail that holds two or more bones or bone parts in a fixed spatial relationship. In this embodiment the exterior of the bone screw shaft is unthreaded. In accordance with the invention, the fixation nail may be adapted for use in the fixation of a variety of bones, including, but not limited to, femur fixations, humerus fixations and tibia fixations.

Referring now to FIG. **10**, there is disclosed a femur fixation nail **1000** disposed within a femur **1002**. The fixation nail has two ends **1004** and **1006** connected by a shaft **1008**. The fixation nail includes a cannulated portion **1010**, which is best seen in the cross-sectional view of FIG. **11**, and fixation nail fenestrations **1012** along the length of the cannulated portion **1010**. One end of the cannulated portion **1010** of the fixation nail **1000** may be configured to accept a nail insert **1020**. This is demonstrated in FIG. **12** which shows a perspective view of the fixation nail **1000** having internal threads **1014** on one end **1004** of the cannulated portion **1010** to promote fixation of a nail insert **1020** having threads **1025** on one end. As shown in the figures, the fixation nail may define one or more bores **1030** through its length through which fixation screws **1040** and **1050** may be passed in order to affix the fixation nail to the bone. The fixation screws may pass through the fixation nail substantially perpendicular to the long axis of the nail or they may pass through the nail at acute or obtuse angles with respect to the long axis of the nail. The dimensions of a fixation screw that passes through the cannulated portion of a fixation nail are desirably selected such that the screw does not substantially impede the passage of a substance to be delivered to the bone. In some instances, the fixation screw may itself include a bore through its length that allows for the passage of the substance.

Referring now to FIG. **13**, there is disclosed a humerus fixation nail **1300** disposed within a humerus **1302**. The fixation nail has two ends **1304** and **1306** connected by a shaft **1308**. The fixation nail includes a cannulated portion **1310**, which is best seen in the cross-sectional view of FIG. **14**, and fixation nail fenestrations **1312** along the length of the cannulated portion **1310**. One end of the cannulated portion **1310** of the fixation nail **1300** may be configured to accept a nail insert **1320**. This is demonstrated in FIG. **15** which shows a perspective view of a nail insert **1320** being inserted into the cannulated portion **1310** of the fixation nail **1300**. The fixation nail **1300** has internal threads (not shown) on one end of its cannulated portion **1310** to promote fixation of the nail insert **1320** which also has threads **1325** on one end.

Referring now to FIG. **16**, there is disclosed a tibia fixation nail **1600** disposed within a tibia **1602**. The fixation nail has two ends **1604** and **1606** connected by a shaft **1608**. The fixation nail includes a cannulated portion **1610**, which is best seen in the cross-sectional view of FIG. **17**, and fixation nail fenestrations **1612** along the length of the cannulated portion **1610**. One end of the cannulated portion **1610** of the fixation nail **1600** may be configured to accept a nail insert. This is demonstrated in FIG. **18** which shows a perspective view of the a nail insert **1620** being inserted into the cannulated portion **1610** of the fixation nail **1600**. The fixation nail **1600** has internal threads (not shown) on one end of its cannulated portion **1610** to promote fixation of the nail insert **1620** which also has threads **1625** on one end. As shown in the figures, the fixation nail need not be straight along its entire length, but may include one or more angles to facilitate the placement of the nail into a bone. The fixation nail may define one or more bores **1630** through its length through which fixation screws **1640**, **1642**, **1644** and **1646** may be passed in order to affix the fixation nail to the bone. The fixation screws may pass through the fixation nail substantially perpendicular to the long axis of the nail or they may pass through the nail at acute or obtuse angles with respect to the long axis of the nail. The bores may be aligned substantially parallel with respect to one another, substantially perpendicular with respect to one another or may be aligned at angles between parallel and perpendicular.

As discussed above, in certain applications it may be desirable that the substance to be delivered to the bone be stored in a reservoir prior to delivery. FIG. **19** discloses one illustrative embodiment of the invention in which an IV **1900** serves as a reservoir for delivering a substance to a tibia via the fixation nail of FIG. **18**. FIG. **20** discloses an alternative embodiment where a pump **2000** serves as the reservoir for delivering a substance to a tibia via the fixation nail of FIG. **18**.

In one embodiment of the invention, the delivery pathway between one or more insert fenestrations and one or more bone screw fenestrations is defined by two balloons, each of which is inflated between the outside of the insert and the inside of the bone screw to form a seal between the insert and the bone screw. This embodiment is exemplified in FIGS. **21** and **22**. FIG. **21** shows a bone screw insert **2100** having a fenestration **2110** along its length. A first balloon **2120** is disposed around the outside of the insert **2100** above the fenestration **2110** and a second balloon **2130** is disposed around the outside of the insert **2100** below the fenestration **2110**. The insert optionally has threads **2140** at one end that interlock with bone screw threads **2150** in a bone screw **2160** to help fix the insert **2100** into the bone screw **2160**. The first and second balloons may be inserted into a bone screw in a deflated state. As shown in FIG. **22**, when the insert is in place inside the bone screw the balloons **2120** and **2130** are disposed above and below one or more fenestrations **2170** in the bone screw. Once the insert is in place, the balloons may be inflated to form a seal between the outside **2180** of the insert **2100** and the inside **2190** of the bone screw **2160**, isolating the insert fenestration **2110** and the bone screw fenestrations **2170** between the balloons. In this manner, the balloons help to define a delivery pathway between one or more insert fenestrations and one or more bone screw fenestrations.

FIG. **23** shows two different bone-screw inserts **2300** and **2310**, each having a pair of balloons **2320**, **2330** and **2340**, **2350** disposed along its length and situated above and below an insert fenestration **2360** and **2370**. The bone-screw inserts have different lengths, such that they may be adapted for insertion into bone screws of different lengths or may be used to isolate fenestrations at different locations along the shaft of a given bone screw. Although the insert and bone screw fenestrations of FIGS. **21-23** are isolated between two inflated balloons, it should be understood that other configurations are possible. For example, one or more insert fenestrations and one or more bone screw fenestrations could be isolated between a single inflated balloon and the top end or the bottom end of the bone screw.

An alternative design for a substance delivery device is shown in FIGS. **24***a* and *b*. In this device a bone screw **2400** is provided with an attachment mechanism, shown as an exterior groove **2410**, running along its length. The bone screw includes a head **2420** that defines a longitudinal bore **2430** having internal threads **2440**. A cannulated insert **2450** adapted to fit through the longitudinal bore **2430** and into the groove **2410** is also provided. The insert includes a head **2460** adapted to accept a tube (not shown), or similar means for delivering a substance, and a plurality of fenestrations **2470** along its length. As shown in FIG. **24***b*, once in place, the insert provides substance delivery pathways along the bone screw from the cannulation at the head **2460** of the insert **2450** through the fenestrations **2470**. In this illustrative embodiment, the insert **2450** does not extend beyond the threads **2480** of the bone screw **2400**. Although not shown in FIG. **24**, the insert may optionally include threads at one end, for example at the bottom of the insert head **2460**, to engage the internal threads **2440** in the bone screw head **2420** to promote fixation of the insert. FIG. **25** shows a perspective view of the delivery device of FIG. **24** connected to a substance delivery tube **2500** and inserted into the hip bone **2510** of a patient.

FIG. **26** depicts a substance delivery device, similar to that of FIG. **25**, where an exterior insert is combined with a fixation nail. FIG. **26***a* shows a cannulated insert **2600** having a head **2610** adapted to receive a tube (not shown), or similar substance delivery means, at one end and a plurality of fenestrations **2620** along its length. As shown in FIG. **26***b*, the insert is adapted to fit into a groove **2630** running along the external surface of a fixation nail **2640**. The fixation nail need not be straight along its entire length, but may include one or more angles to facilitate the placement of the nail into a bone. The fixation nail may define one or more bores **2650** through its length through which bone screws (not shown) may be inserted to fix the nail to the bone. In addition, the fixation nail may itself include one or more fenestrations **2660** along its length. FIG. **27** shows a perspective view of the delivery device of FIG. **26***b* inserted into the tibia **2700** of a patient.

Another aspect of the present invention is a method of administering a substance to a bone. In one embodiment, the method comprises introducing a cannulated, fenestrated bone screw into a bone, introducing a cannulated insert into the bone screw, and introducing a substance to be delivered into the cannulated portion of the insert. In another embodiment, the method comprises attaching a cannulated insert along at least a portion of an exterior surface of a bone screw, introducing the bone screw into a bone, and introducing a substance to be delivered into the cannulated portion of the insert. Under some circumstances, one may find it advantageous to introduce the insert into or along the bone screw, in its entirety or only partially, prior to introducing the bone screw into the bone. This sequence might be preferred in order to shorten the overall surgery time, or to reduce the amount of material that enters the bone-screw fenestrations from outside the screw during screw insertion, for example. Alternately, other circumstances may make it more advantageous to introduce the insert into the bone screw, in its entirety or only partially, after the bone screw is introduced into the bone. This latter sequence might be preferred in order to be able to determine which screw fenestrations or exterior insert attachment mechanisms (e.g. grooves) are located at the optimum location for delivery of the desired substance, and thus what insert configuration or length should be used to facilitate substance delivery to desired locations in or near a bone. Other sequences can be envisioned by one skilled in the art, such as for example, partially introducing the bone screw into a bone, partially or completely inserting the insert into or along the bone screw, and then completing the insertion of the bone screw into the bone. Even more sequence variations are possible when one considers the additional step of introducing the substance into the cannulated portion of the bone screw insert, and all such sequence variations are to be included within the scope of this disclosure.

In practicing the current invention it may also be found advantageous to drill a pilot hole in the one or more bones or bone pieces in order to facilitate introduction of the bone screw. In this regard it may be found advantageous to use bone screws with self-tapping threads, or to pre-cut the threads in the bone prior to bone screw insertion.

When the bone screw is a fixation screw, the present invention may further comprise the method of holding or fixing two or more bones or bone pieces in a fixed spatial relationship with respect to each other. Such a method may be desirable when it is desired to deliver a substance such as a medicant or therapeutic to the vicinity of a site where a peripheral skeletal fracture or an osteotomy is mended, a spondyloysis or an odontoid fracture repaired, or lumbar facet joints are fused.

The present invention may further comprise the method of delivering a substance to the vicinity of a bone including the steps of attaching a reservoir, a pump, or both, to the bone screws or bone-screw inserts disclosed herein. Such reservoirs and pumps may aid in the continuous, regulated, or long-term delivery of the desired substance to the vicinity of a bone, thereby facilitating the healing process or the overall health of the bone and its surrounding tissues.

The bone screw and insert embodiments disclosed herein may be configured to allow for re-sealing and multiple time or multiple use access to the cannulated portion of the bone screw or insert. In the exemplary embodiment of FIG. **28**, a bone screw **2800** is shown inserted or disposed within a bone **2810**. An insert **2820** is shown inserted within bone screw **2800**. A seal, shown as an insert cap **2830**, is coupled to the outer or proximal end of insert **2820**. In the embodiment shown, insert cap **2830** is an end cap directly coupled to the inner surface of insert **2820**. Insert cap **2830** acts to seal the outer or proximal end of insert **2820**. In other embodiments, the seal may be positioned along the shaft of the insert. In some embodiments, cap **2830** is removably coupled to insert **2820**, and in other embodiments, cap **2830** may be coupled to insert **2820** via a non-removable (i.e., permanent) coupling. A fluid delivery device, shown as syringe **2840**, includes a needle **2850**.

Referring to FIG. **29**(*a*) and FIG. **29**(*b*), a schematic cross-sectional view of insert **2820** is shown according to an exemplary embodiment. Insert **2820** includes a shaft **2822**, an opening **2824** located at the proximal end of insert **2820**, and at least one insert fenestration **2826** located through shaft **2822**. The shaft **2822** of insert **2820** also includes a cannulation **2828** formed along at least a portion of shaft **2822**. In the embodiment shown, opening **2824** is located at one end of cannulation **2828**. As shown in FIG. **29**(*a*) and FIG. **29**(*b*), the opening **2824** of insert **2820** is closed or sealed by cap **2830**. In this arrangement, cap **2830** includes an inner surface facing or in communication with cannulation **2828**. Cap **2830** may be coupled to or attached to insert **2820** by any suitable means. For example, cap **2830** may be threaded to mate with threads located within opening **2824**, and, in other embodiments, cap **2830** may be press fit into opening **2824** or may be attached to opening **2824** with an adhesive. In another embodiment, opening **2824** may be

located along the sidewall of the insert, and cap **2830** may seal the opening along the sidewall of the insert.

As discussed above, a substance may be placed in the cannulated portion of an insert, such as insert **2820**, so that the substance may be delivered through the insert fenestrations and through the bone screw fenestrations to the bone. In an exemplary embodiment, insert cap **2830** is able to provide multiple-time or reusable access to cannulation **2828** of the insert following implantation of the bone screw/insert combination into the bone. In the exemplary embodiment of FIG. **29**(*a*) and FIG. **29**(*b*), reusable, post-implantation access to cannulation **2828** of insert **2820** is provided by self-sealing cap **2830**. In this embodiment, cap **2830** comprises a resilient, self-sealing material, and needle **2850** pierces through cap **2830** providing access to cannulation **2828**. As shown in FIG. **29**(*a*), needle **2850** creates a perforation **2834** that extends through cap **2830**. With needle **2850** located within cannulation **2828**, a substance **2832** may be delivered from the fluid delivery device into cannulation **2828**. With substance **2832** within cannulation **2828**, the substance may be delivered through insert fenestrations **2826** and through bone screw fenestrations as discussed in the various embodiments above.

As shown in FIG. **29**(*b*), once substance **2832** is delivered to insert **2820**, needle **2850** may be removed or withdrawn from cap **2830**. Once needle **2850** is withdrawn, perforation **2834** self-seals to prevent substance **2832** from flowing out of the proximal end of insert **2820** through perforation **2834**. The process of inserting needle **2850** through cap **2830** may be repeated as necessary to deliver multiple doses of a substance to insert **2820**. While the fluid delivery device is shown in FIG. **28** as syringe **2840**, in various other embodiments, needle **2850** may be connected to a variety of fluid delivery devices. For example, the fluid delivery device may be a pump (e.g., an infusion pump) or a bag or reservoir or fluid bag (similar to an IV bag) coupled to needle **2850** via tubing. In one embodiment, the fluid delivery device may be a micro-infusion device in fluid communication with the cannulated portion of the insert and/or bone screw. In this embodiment, the micro-infusion pump may be worn by a user, and a substance may be continuously delivered through the bone screw and/or insert to promote bone growth.

In various embodiments, cap **2830** may be made from any material or combination of materials that provides for resealing or self-sealing. In various embodiments, cap **2830** may be made from a compliant, non-rigid or resilient material that resiliently expands following withdrawal of needle **2850** to seal perforation **2834** caused by needle **2850**. In one embodiment, cap **2830** may be made from a surgical, self-sealing rubber or polymer, such as surgical silicone rubber.

The post-implantation access to cannulation **2828** of insert **2820** provided by cap **2830** may allow the user to deliver a new or second substance or additional doses of a same substance to the bone as needed to treat a particular patient. For example, following implantation of the bone screw/insert combination, separate doses of antibiotics may be delivered to a fracture site via insert **2820**. In another embodiment, insert **2820** may be used for repeated delivery of cancer treating drugs (e.g., anti-cancer drugs) to the bone in which the bone screw is implanted. In another embodiment, bone morphogenic proteins may be delivered in separate doses to the bone via insert **2820**. In other embodiments, any other substance that may be intermittently delivered to a patient may be delivered using insert **2820**. Further, in contrast to single-use delivery devices, repeatable access and multiple time delivery via insert **2820** may be useful in adjusting or changing the substances delivered via insert **2820**. For example, insert **2820** and resealing cap **2830** allow the user to change either the dose or the type of substance delivered to a patient each time needle **2850** is inserted through cap **2830**. In addition, post-implantation access to cannulation **2828** of insert **2820** by needle **2850** may allow for the post-implantation connection of any desired fluid delivery device (e.g., an IV or infusion pump) to the insert by connecting the fluid delivery device to needle **2850**. This may allow the user to switch or change the type of fluid delivery device used to deliver fluid to the bone via the bone screw/insert combination. In other embodiments, needle **2850** may also be connected to a material removal device allowing for repeat and resealing access through cap **2830** for removal of material from cannulation **2828** of insert **2820**, as described below in relation to FIGS. **30**(*a*) and **30**(*b*).

To deliver a dose of substance to a patient by piercing cap **2830** with needle **2850**, the user will need to align needle **2850** with cap **2830** following implantation of the implanted bone screw/insert combination. In some embodiments, the bone screw/insert combination may be located a small distance below the skin such that cap **2830** may be palpated through the skin allowing the user to align the needle with cap **2830** by touch. In other embodiments, the bone screw/insert combination may be located in a bone deeper below the skin such that alignment via palpation may be difficult or impossible. In such an embodiment, needle **2850** may be aligned with cap **2830** by imaging the location of the cap **2830** via a suitable imaging device (e.g., via X-ray, CT, etc.).

While the embodiment shown in FIGS. **28**, **29**(*a*) and **29**(*b*) shows the resealing cap coupled to an insert, it should be understood that in other embodiments cap **2830** may be coupled directly to a cannulated bone-screw to seal the proximal opening of a bone-screw. For example, as shown in FIG. **29**(*c*), bone screw **2800** may include a resealing cap, shown as bone screw cap **2860** (similar to cap **2830**), that is coupled to or attached to bone screw **2800** such that bone screw cap **2860** seals the proximal opening **2862** of bone screw **2800**. Similar to the other bone screw embodiments discussed herein, bone screw **2800** includes a bone screw cannulation **2864** and bone screw fenestrations **2866**. With needle **2850** extending through cap **2860**, material may be delivered to a bone through bone screw fenestrations **2866**, and, as discussed below, material may be removed from the bone through bone screw fenestrations **2866**. As shown in FIG. **29**(*c*), bone screw cap **2860** may seal bone screw **2800** without an insert disposed within a bone screw cannulation **2864**. In another embodiment, bone screw cap **2860** may seal the proximal opening **2862** of bone screw **2800** with an insert disposed within bone screw cannulation **2864**. Further, it should be understood that various embodiments of resealing caps **2830**, **2860** may be used with any of the bone screw and insert embodiments discussed herein.

In other embodiments, the bone screw and insert embodiments disclosed herein may be used as part of a material or tissue removal system. In the exemplary embodiment of FIG. **30**(*a*) and FIG. **30**(*b*), a material removal system **2900** is shown according to an exemplary embodiment. Material removal system **2900** includes a bone screw **2910**, a bone screw insert **2930** and a material removal device, shown as suction device **2950** (e.g., a pump, vacuum, etc.). Bone screw **2910** includes a sidewall **2912**, a threaded portion, shown as threads **2914**, formed on the inner surface of sidewall **2912**, and a bone screw cannulated portion **2916**. Bone screw **2910** also includes at least first fenestrations **2918** and second fenestrations **2920**. In the orientation of

FIG. **30**(*a*), fenestrations **2918** are located above (i.e., closer to the proximal end of bone screw **2910**) fenestrations **2920**.

Insert **2930** includes a first expandable portion, shown as first balloon **2932**, and a second expandable portion, shown as second balloon **2934**. Insert **2930** includes an insert fenestration **2936** located between balloons **2932** and **2934**. As discussed above regarding FIGS. **21-23**, balloons **2932** and **2934** may be inflated to form seals with the inner surface of bone screw **2910** to provide for isolation of one or more of the bone screw fenestrations. Insert **2930** includes a threaded portion, shown as threads **2938**, that engages with threads **2914** of bone screw **2910**. While material removal system **2900** is shown and described with an insert that includes expandable sections, it should be understood that material removal system **2900** may utilize any of the bone screw/insert combinations discussed herein.

Material removal system **2900** includes a material removal device, shown as suction device **2950**, connected to insert **2930** via a tubing **2952**. Suction device **2950** is configured to extract or aspirate material from cannulated portion **2916** of the bone screw and from the area surrounding the bone screw. In various embodiments, suction device **2950** may be a motorized suction device or may be a manual suction device (e.g., a syringe). In the embodiment shown in FIG. **30**(*a*), balloons **2932** and **2934** are inflated to isolate fenestrations **2918**. As illustrated by arrows **2954**, suction device **2950** applies a vacuum to insert **2930** via tubing **2952** such that material is drawn in through fenestrations **2918** and is moved through the insert and tubing to reach the suction device. Thus, in this manner, suction device **2950** allows for removal or harvesting of material adjacent fenestrations **2918**.

Various types of material may be removed from a patient using material removal system **2900**. In addition, material may be removed for various purposes, including for diagnostic testing and/or for subsequent implantation. For example, in one embodiment, bone marrow may be harvested using material removal system **2900** to be used for bone marrow donation or for diagnostic testing. Other materials, such as blood, may be removed for diagnostic testing. In some embodiments, various materials may be removed from the bone screw using suction device **2950** to test for the presence of infection within the bone at the site of implantation of the bone screw.

In one embodiment, material removal system **2900** may be used to harvest osteoprogenitor cells from the bone of the patient into which bone screw **2910** is inserted. In one such embodiment, the harvested osteoprogenitor cells harvested using material removal system **2900** may then be implanted into another area of the patient (e.g., another bone) where bone growth is desired. In one specific embodiment, material removal system **2900** may be used to remove osteoprogenitor cells from one location in a patient, and then the removed osteoprogenitor cells may be implanted using one of the bone screw/insert combinations discussed herein located at another position within the patient. In various embodiments, the osteoprogenitor cells may be combined with other materials (e.g., calcium phosphate, hydroxylapatite, demineralized bone matrix, etc.) that may facilitate or enhance bone growth that results from the osteoprogenitor cells.

As shown in FIG. **30**(*a*) and FIG. **30**(*b*), bone screw **2910** includes a plurality of fenestrations (e.g., fenestrations **2918** and **2920**). As used as part of material removal system **2900**, insert **2930** and the plurality of fenestrations of bone screw **2910** allow the user to select or to isolate individual fenestrations or groups of fenestrations to selectably harvest material through the selected fenestrations. For example, in FIG. **30**(*a*), insert **2930** is shown harvesting material through fenestrations **2918**. In FIG. **30**(*b*), insert **2930** is shown positioned within bone screw **2910** such that fenestrations **2920** are isolated between balloons **2932** and **2934**. In this position, operation of suction device **2950** allows for removal of material through fenestrations **2920**, as depicted by arrows **2956**. This arrangement allows the user to selectively take samples of removed material from various positions within the bone.

In one embodiment, insert **2930** may include a resealing cap, such as cap **2830**, that allows suction device **2950** to be connected to the cannulated portion of the insert via a needle, such as needle **2850**. In other embodiments, the material removal device may be a device other than a suction-based aspiration device. For example, the material removal device may be any other suitable material removal device such as an absorbent device (e.g., a swab) that absorbs material located within either the cannulated portion of the bone screw or the insert.

In other embodiments, a bone screw may include one or more fenestrations shaped as a slot extending longitudinally along the shaft of a bone screw. Referring to FIG. **31**, bone screw **3000** is shown according to an exemplary embodiment. Bone screw **3000** includes a shaft **3010** and bone screw threads **3020**. Bone screw **3000** includes a cannulation **3030**, a first fenestration **3040**, a second fenestration **3050**, and a third fenestration **3060**. First fenestration **3040** and second fenestration **3050** are configured as rectangular slots that extend in the longitudinal direction along shaft **3010**. In the embodiment shown, the length of first fenestration **3040** in the longitudinal direction is approximately a quarter of the longitudinal length of shaft **3010** and the length of second fenestration **3050** in the longitudinal direction is approximately half of the longitudinal length of shaft **3010**. Third fenestration **3060** is shown as a smaller slot-shaped fenestration located near the distal end of bone screw **3000**.

In other embodiments, fenestrations, such as fenestrations **3040**, **3050** and **3060**, may be of other lengths relative to shaft **3010** (e.g., ⅛ of the length of shaft **3010**, ¼ of the length of shaft **3010**, ½ of the length of shaft **3010**, and ¾ of the length of shaft **3010**, etc.). In the embodiment shown in FIG. **31**, threads **3020** are shown including gaps or spaces at the location of fenestrations **3040**, **3050** and **3060**. In other embodiments, threads **3020** may be contiguous threads that extend above or overlap fenestrations **3040**, **3050** and **3060**.

Referring to FIG. **32**, a femur fixation nail **3100** disposed within a femur **1002** is shown. Fixation nail **3100** includes a shaft **3110** which is cannulated. Fixation nail **3100** is similar to fixation nail **1000** shown in FIG. **10** except that fixation nail **3100** includes three rectangular-shaped slot fenestrations **3120**, **3130** and **3140** that extend in the longitudinal direction along shaft **3110**. In the embodiment shown, all of the fenestrations **3120**, **3130** and **3140** are generally of the same size and shape.

It should be understood that while FIGS. **31** and **32** show two bone screw embodiments including slot-shaped fenestrations, any of the bone screw embodiments discussed herein may include one or more slot-shaped fenestrations. Further, while the bone screw embodiments of FIGS. **31** and **32** show bone screws having three slot-shaped fenestrations, it should be understood that the bone screw embodiments may include any number of slot-shaped fenestrations (e.g., 1, 2, 4, 5, 6, 7, 8, etc.) as needed for a particular application, procedure, patient, etc. While in the exemplary embodiments the slot-shaped fenestrations are shown as rectangular in shape, other shapes may be used (e.g., oval, elliptical,

diamond, triangular, etc.). Further, while FIGS. **31** and **32** depict slot-shaped fenestrations with longitudinal axes extending in the direction of the longitudinal axis of the shaft of the bone screw, slot-shaped fenestrations may assume other positions or orientations relative to the shaft of the bone screw. In one exemplary embodiment, a slot-shaped fenestration may be a circumferentially oriented fenestration such that the longer axis of the fenestration is perpendicular to the longitudinal axis of the shaft (as shown in FIG. **10**).

Referring to FIG. **33**(*a*), FIG. **33**(*b*) and FIG. **33**(*c*), a bone screw **3210** is shown implanted or disposed within a bone **3200**. Bone screw **3210** includes a sidewall **3212**, a threaded portion, shown as threads **3214**, formed on the inner surface of sidewall **3212**, and a bone screw cannulated portion **3216**. As shown, bone screw **3210** includes first fenestrations **3218** and second fenestrations **3220**. Fenestrations **3218** and **3220** are slot-shaped fenestrations that extend longitudinally along sidewall **3212**. Bone screw **3210** may be a threaded bone screw, such as bone screw **3000**, a fixation nail, such as femur fixation nail **3100**, or any other bone screw embodiment disclosed herein. In the orientation of FIG. **33**(*a*), fenestrations **3218** are located above (i.e., closer to the proximal end of bone screw **3210**) fenestrations **3220**.

An insert **3230** is shown positioned within cannulated portion **3216** of bone screw **3210**. Insert **3230** includes a first expandable portion, shown as first balloon **3232**, and a second expandable portion, shown as second balloon **3234**. Insert **3230** includes an insert fenestration **3236** located between balloons **3232** and **3234**. In the embodiment shown in FIGS. **33**(*a*), **33**(*b*) and **33**(*c*), the longitudinal length, L**1**, of fenestrations **3218** and/or the longitudinal length, L**2**, of fenestrations **3220** are greater than the longitudinal length, L**3**, of the portion of insert **3230** that is located between first balloon **3232** and second balloon **3234**.

The relative sizing of fenestrations **3218** and **3220** and the portion of the insert between the upper and lower balloons allows for selection or isolation of a portion of slot-shaped fenestrations **3218** and **3220**. As shown in FIG. **33**(*a*), insert **3230** may be positioned such that insert fenestration **3236** is located adjacent the upper ends of fenestrations **3218**. With insert **3230** in this position, balloons **3232** and **3234** may be inflated to provide for isolation or selection of the upper portions of fenestrations **3218**. With the upper portions of fenestrations **3218** isolated, a substance may be delivered through insert fenestration **3236** to the portion of bone **3200** adjacent the isolated section of fenestrations **3218**, and/or a material may be removed from the portion of bone **3200** adjacent the isolated section of fenestrations **3218** via insert **3230**, as discussed in the various embodiments above.

In general, upper balloon **3232** is expanded to form an upper seal between the outer surface of the balloon and the inner surface of the bone screw and/or the tissue adjacent the bone screw fenestration, and lower balloon **3234** is expanded to form a lower seal between the outer surface of the balloon and the inner surface of the bone screw and/or the tissue adjacent the bone screw fenestration. Thus, with the balloons expanded, the lower surface of upper balloon **3232** and the upper surface of lower balloon **3234** define a sealed chamber or section **3242** that isolates a portion of the adjacent bone screw fenestration. Insert fenestration **3236** is located within sealed section **3242**, and thus, a pathway is defined between the portion of bone **3200** adjacent the sealed section **3242** and the proximal end of insert **3230**. A substance may be delivered to bone **3200** via the pathway and/or a material may be removed from bone **3200** via the pathway as discussed above in the various embodiments.

Each of FIGS. **33**(*a*), **33**(*b*), and **33**(*c*) show the isolation of various portions of fenestrations **3218** according to various exemplary embodiments. In the position shown in FIG. **33**(*a*), upper balloon **3232** is expanded to form an upper seal with the inner surface of bone screw **3210** above fenestrations **3218**, and lower balloon **3234** is expanded to form a lower seal with both the tissue (e.g., bone **3200**) adjacent to fenestrations **3218** and with the inner surface of bone screw **3210** that is laterally adjacent to fenestrations **3218** (not visible in the section view of FIG. **33**(*a*)). In the position shown in FIG. **33**(*b*), both upper balloon **3232** and lower balloon **3234** are expanded to form seals with the tissue (e.g., bone **3200**) adjacent to fenestrations **3218** and with the inner surface of bone screw **3210** that is laterally adjacent to fenestrations **3218** (not visible in the section view of FIG. **33**(*b*)). In the position shown in FIG. **33**(*c*), lower balloon **3234** is expanded to form a lower seal with the inner surface of bone screw **3210** below fenestrations **3218**, and upper balloon **3232** is expanded to form an upper seal with both the tissue (e.g., bone **3200**) adjacent to fenestrations **3218** and with the inner surface of bone screw **3210** that is laterally adjacent to fenestrations **3218** (not visible in the section view of FIG. **33**(*c*)). Also as shown in FIG. **33**(*c*), an upper portion of balloon **3234** is shown expanding to seal against the lower surface **3238** of fenestrations **3218** by expanding through laterally through fenestration **3218**. It should be understood that, both balloons **3232** and **3234** may be configured to allow for expansion through the fenestrations to provide for sealing as shown in FIG. **33**(*c*).

While FIGS. **33**(*a*), **33**(*b*), and **33**(*c*) show three exemplary positions at which insert **3230** may be used to isolate portions of fenestrations **3218**, it should be understood that insert **3230** may be moved to any position relative to the fenestration as desired by the user. In the embodiment shown, the positioning may be selected by advancing insert **3230** through threads **3214** of bone screw **3210** via cooperation of insert threads **3240**. While FIGS. **33**(*a*), **33**(*b*) and **33**(*c*) depict selection of various portions of fenestrations **3218**, it should be understood that insert **3230** may be sized and configured such that portions of any fenestration of bone screw **3210** may be selected as discussed above.

Further modifications and alternative embodiments of various aspects of the invention will be apparent to those skilled in the art in view of this description. Accordingly, this description is to be construed as illustrative only. The construction and arrangements of the bone screws and inserts, as shown in the various exemplary embodiments, are illustrative only. Although only a few embodiments have been described in detail in this disclosure, many modifications are possible (e.g., variations in sizes, dimensions, structures, shapes and proportions of the various elements, values of parameters, mounting arrangements, use of materials, colors, orientations, etc.) without materially departing from the novel teachings and advantages of the subject matter described herein. Some elements shown as integrally formed may be constructed of multiple parts or elements, the position of elements may be reversed or otherwise varied, and the nature or number of discrete elements or positions may be altered or varied. The order or sequence of any process, or method steps may be varied or re-sequenced according to alternative embodiments. Other substitutions, modifications, changes and omissions may also be made in the design, operating conditions and arrangement of the various exemplary embodiments without departing from the scope of the present invention.

What is claimed is:

1. A system for treating a bone, comprising:

an insert for a bone screw comprising:

a shaft extending between proximal and distal ends of the insert, wherein the shaft comprises an opening in the proximal end and is closed at the distal end, and a cannulation extending from the opening through at least a portion of the shaft, wherein the shaft further comprises a fenestration disposed along the cannulation such that the cannulation is configured to provide a pathway for a substance between the opening and the fenestration; and

a cap fastened to and sealing the opening in the proximal end of the shaft and adjoining the cannulation, wherein the cap is configured to provide access by a needle through the cap to the cannulation following implantation of the system within the bone and is further configured to self-seal after the needle is removed;

wherein the insert comprises a threaded coupling portion on the shaft configured to engage with a compatible threaded coupling portion of the bone screw to fasten the insert and the bone screw together.

2. The system of claim 1, wherein the cap comprises at least one of a rubber and a polymer that is configured to self-seal following puncture through the cap by the needle.

3. The system of claim 2, wherein the cap comprises surgical silicone rubber.

4. The system of claim 1, further comprising the bone screw, wherein the bone screw comprises first and second ends connected by a shaft, wherein the shaft of the bone screw is cannulated, wherein the insert is configured to be received in the cannulation of the bone screw, and wherein the insert is movable within the cannulation of the bone screw.

5. The system of claim 4, wherein the insert is movable within the cannulation of the bone screw between:

a first position wherein a portion of the bone screw at least partially blocks the fenestration of the insert, limiting the substance from exiting the cannulated portion of the insert via the fenestration of the insert; and

a second position wherein the insert provides a delivery pathway for the substance between the proximal end of the insert and a fenestration of the bone screw to the exterior of the bone screw.

6. The system of claim 4, further comprising:

the needle configured to extend through the cap;

the substance, wherein the substance comprises at least one of bone morphogenic proteins, osteoprogenitor cells, calcium phosphate, antibiotics, and anti-cancer drugs; and

a delivery device coupled to the needle and configured to provide the substance through the needle, past the cap, and into the cannulation of the insert;

wherein the delivery device comprises at least one of a syringe, a pump, and a fluid bag.

7. The system of claim 4, further comprising:

the needle configured to extend through the cap; and

a suction device coupled to the needle for removing the substance from the bone.

8. The system of claim 1, wherein the threaded coupling portion on the shaft of the insert comprises a male threaded coupling and the compatible threaded coupling portion of the bone screw comprises a female threaded coupling.

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